

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Evaluation of Bioequivalence of Fenofibrate 200 mg in Healthy Volunteers

#### Protocol summary

##### Study aim

The aim of this report is comparison of pharmacokinetic parameters of Fenofibrate 200 mg manufactured by Aani Darman versus Abbot in 24 healthy volunteers in vivo and in vitro. Statistical data analysis and finding if the Aani Darman product is proper or not.

##### Design

Subjects were simple randomized to either of the two treatment arms (test or reference) separated by a washout period of 7 days. Each subject is randomly allocated to either an AB sequence or a BA sequence.

##### Settings and conduct

In a crossover study, each subject receives both drugs (T and R); one in one subgroup of the study and the other in a second subgroup. Essentially, subjects in a crossover study are randomly assigned to one of two sequence groups. Subjects in sequence group 1 (i.e., AB) receive the test drug first, followed by the reference drug. Subjects in sequence group 2 (i.e., BA) receive the reference drug first, followed by the test drug. there is a one week washout period between two subgroups.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18 to 55 years old, Males and/or non-pregnant, non-lactating females, having a physical examination with no clinically significant finding and laboratory normal tests, do not take any chronic or acute medication for at least 1 week before the start of the study, no history of diseases affecting the pharmacokinetic processes of the drug. Exclusion criteria is described in the related part.

##### Intervention groups

Administration of fenofibrate test from Iranian manufacture and reference to healthy volunteers in two subgroup. The intervention is only one dose test or reference in first week and in the next week vise versa.

##### Main outcome variables

Area Under plasma Concentration(AUC) 0 to t, AUC 0 to infinite, Peak Concentration( C<sub>max</sub>), time to peak concentration( t<sub>max</sub>)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221002056075N2**

Registration date: **2023-05-14, 1402/02/24**

Registration timing: **retrospective**

Last update: **2023-05-14, 1402/02/24**

Update count: **0**

##### Registration date

2023-05-14, 1402/02/24

##### Registrant information

##### Name

Sima Sadrai

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 9054

##### Email address

sadrai@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-02-09, 1401/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Bioequivalence of Fenofibrate 200 mg in

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthy Volunteers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | allocated to either an AB sequence or a BA sequence.                                                                                              |
| <b>Public title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Blinding (investigator's opinion)</b>                                                                                                          |
| Bioequivalence of Fenofibrate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Double blinded                                                                                                                                    |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Blinding description</b>                                                                                                                       |
| Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | The dosage forms are in boxes and the volunteers should not see what he or she takes. The coding of samples are only by code of subject and date. |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Placebo</b>                                                                                                                                    |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Not used                                                                                                                                          |
| 18 to 55 years old, Males and/or non-pregnant, non-lactating females Body mass index (BMI) from 18.5 to 24.9 weight in kg/(height in meter), ability to communicate effectively with study personnel and willingness to follow the protocol requirements as evidenced by written informed consent having a physical examination with no clinically significant finding and laboratory normal tests, do not take any chronic or acute medication for at least 1 week before the start of the study no history of diseases affecting the pharmacokinetic processes of the drug                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Assignment</b>                                                                                                                                 |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Crossover                                                                                                                                         |
| History of allergic responses to related drugs, or any of its formulation ingredients, have significant diseases (which might compromise the haemopoietic, gastrointestinal, renal, hepatic, cardiovascular, respiratory, central nervous system, diabetes, psychosis or any other body system) or clinically significant abnormal findings during screening, history or presence of bronchial asthma history or evidence of drug dependence or of alcoholism or of moderate alcohol use, smokers who smoke 10 or more cigarettes per day or those who cannot refrain from smoking during the study period, history of difficulty with donating blood or difficulty in accessibility of veins, history of difficulty in swallowing, or of any gastrointestinal disease which could affect drug absorption. volunteers who have received a known investigational drug within five elimination half-life of the administered drug prior to the initial dose of study drug or who have participated in a clinical drug study or bioequivalence study within 90 days prior to the initial dose of study drug, whichever is greater, found positive in urine test for drugs of abuse done before check-in of period, | <b>Other design features</b>                                                                                                                      |
| <b>Age</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | no                                                                                                                                                |
| From 18 years old to 55 years old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Secondary Ids</b>                                                                                                                              |
| <b>Gender</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | empty                                                                                                                                             |
| Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Ethics committees</b>                                                                                                                          |
| <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>1</b>                                                                                                                                          |
| Bioequivalence                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Ethics committee</b>                                                                                                                           |
| <b>Groups that have been masked</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Name of ethics committee</b>                                                                                                                   |
| <ul style="list-style-type: none"> <li>Participant</li> <li>Outcome assessor</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Ethics Committees of The Institute of Pharmaceutical Sciences -Tehran University of Medical Sciences                                              |
| <b>Sample size</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Street address</b>                                                                                                                             |
| Target sample size: 24                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | The Institute of Pharmaceutical Sciences -Tehran University of Medical Sciences                                                                   |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>City</b>                                                                                                                                       |
| Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Tehran                                                                                                                                            |
| <b>Randomization description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Province</b>                                                                                                                                   |
| Subjects were simple randomized to either of the two treatment arms (test or reference) separated by a washout period of 7 days. The standard 2 × 2 crossover design is used to assess between two groups (test group A and control group B). Each subject is randomly                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Tehran                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Postal code</b>                                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ۱۴۱۷۶۱۴۴۱۱                                                                                                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Approval date</b>                                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 2022-10-02, 1401/07/10                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Ethics committee reference number</b>                                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IR.TUMS.TIPS.REC.1401.056                                                                                                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Health conditions studied</b>                                                                                                                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>1</b>                                                                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Description of health condition studied</b>                                                                                                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | comparison of test and reference fenofibrate                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>ICD-10 code</b>                                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>ICD-10 code description</b>                                                                                                                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Primary outcomes</b>                                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>1</b>                                                                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Description</b>                                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Comparison of plasma profile of test versus reference drug                                                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Timepoint</b>                                                                                                                                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | From administration of drug since 48 hour                                                                                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Method of measurement</b>                                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | with HPLC                                                                                                                                         |

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The test (Aani darman company from Iran) fenofibrate 200 milligram capsules by a crossover design is given only once to the same volunteers. There we have a washout period (one week). Fenofibrate is used to treat primary hypercholesterolemia, mixed dyslipidemia, severe hypertriglyceridemia. Only the volunteers are by a simple randomizing divided to two groups. So we have a sequence effect. Group A, first test and next week reference. Group B, first reference and next week test.

#### Category

Other

### 2

#### Description

Control group: The reference (Abbot company, from USA, with brand name of Lipantyl) fenofibrate 200 milligram capsules by a crossover design is given only once to the same volunteers. There we have a washout period (one week). Only the volunteers are by a simple randomizing divided to two groups. So we have a sequence effect. Group A, first test and next week reference. Group B, first reference and next week test.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Healthy volunteers in the School of Pharmacy

##### Full name of responsible person

Sima Sadrai

##### Street address

Post Box 14155/6451, School of Pharmacy, Tehran  
University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۷۶۱۴۴۱۱

##### Phone

+98 21 6695 9054

##### Fax

+98 21 6646 1178

##### Email

sadrai@tums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Aani Darman Pharmaceutical Company

##### Full name of responsible person

Dr Monir Saadat Ahmadi

##### Street address

No. 243,244, Golestan 9, Baharestan Industrial  
Township, Karaj

##### City

Alborz

##### Province

Alborz

##### Postal code

3197994602

##### Phone

+98 26 3762 1740

##### Fax

+98 26 3762 1750

##### Email

Ahmadi@aanidarman.com

##### Web page address

<http://www.aanidarman.com>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Aani Darman Pharmaceutical Company

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Industry

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Sima Sadrai

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

P.O.Box 14155/6451, School of Pharmacy, Tehran  
University of Medical Sciences, Tehran

##### City

Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۱۷۶۱۴۱۱  
**Phone**  
+98 21 6695 9054  
**Fax**  
+98 21 6646 1178  
**Email**  
sadrai@tums.ac.ir  
**Web page address**  
<http://www.tums.ac.ir>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Sima Sadrai  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
P.O.Box, 14155/6451, School of Pharmacy, Tehran  
University of Medical Sciences, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۱۷۶۱۴۴  
**Phone**  
+98 21 6695 9054  
**Fax**  
+98 21 6646 1178  
**Email**  
sadrai@tums.ac.ir  
**Web page address**  
<http://www.tums.ac.ir>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Sima Sadrai  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
P.O.Box, 14155/6451, School of Pharmacy, Tehran  
University of Medical Sciences, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۱۷۶۱۴۴  
**Phone**  
+98 21 6695 9054  
**Fax**  
+98 21 6646 1178  
**Email**  
sadrai@tums.ac.ir  
**Web page address**  
<http://www.tums.ac.ir>

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

It is order of a pharmaceutical company.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available