Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

In vivo Bioequivalence study of Aspirin 81mg tablet manufactured by Aani Darman Pharmaceutical Co. Compared to innovator Product

Protocol summary

Study aim
In vivo fasted-state bioequivalence study of Aspirin 81 mg tablet

Design
The clinical trial has control and test groups with crossover, randomized design, without blinding. 24 healthy male volunteers will participate randomly in the study as two twelve-person groups. Each volunteer will receive a single dose in two periods. In one period the test and in another period the reference formulation. Therefore, each volunteer will be his own "Control". To randomly assign participants in two groups, the lottery method will be used.

Settings and conduct
After oral administration of one 81-mg tablet to volunteer, the blood samples will be collected in predetermined time intervals up to 24 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: General Health (in terms of Liver, Heart and Kidney diseases), Age (18-59 years old) Exclusion criteria: Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy

Intervention groups
Intervention group will receive a single oral dose of test drug product (Aspirin 81 mg tablet manufactured by Aani Darman, Iran) and Control group will receive a single dose of reference drug product (Aspirin 81 mg tablet manufactured by Bayer, USA). Blood samples will be taken from the volunteers for 24 hours at the mentioned time points after drug administration and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively).

Main outcome variables
Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220211053992N6**
Registration date: **2023-01-09, 1401/10/19**
Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**
Update count: **0**

Registration date
2023-01-09, 1401/10/19

Registrant information

Name
Hadi Valizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 8801

Email address
valizadehh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-10, 1401/10/20

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo Bioequivalence study of Aspirin 81mg tablet manufactured by Aani Darman Pharmaceutical Co. Compared to innovator Product

Public title

In vivo Bioequivalence study of Aspirin tablet

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

General Health (in terms of Liver, Heart and Kidney diseases) Age between 18 to 60 years

Exclusion criteria:

Smoking, History of cardiovascular, liver, and kidney disease Pregnancy Alcohol and drug addiction History of drug allergy

Age

From **18 years** old to **59 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Research Committe, Tabriz University of Medical Sciences

Street address

Faculty of Pharmacy, University of Medical Sciences,Golgasht st Attar Neishaboori st. Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2022-12-19, 1401/09/28

Ethics committee reference number

IR.TBZMED.REC.1401.855

Health conditions studied

1

Description of health condition studied

In the present study, the products will be administered to healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of drug

Timepoint

0.5-24 hours in predetermined time intervals after drug administration

Method of measurement

HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group will receive a single oral dose of test product (Aspirin 81mg sachet manufactured by Aani Darman Co., Iran) in fasted state. Blood samples will be collected for 24 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

Category

Treatment - Drugs

2

Description

Control group: Control group will receive a single oral

dose of reference product (Åspirin 81mg tablet manufactured by Bayer, USA) in fasted state. Blood samples will be collected for 24 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences, Faculty of Pharmacy

Full name of responsible person
Hadi Valizadeh

Street address
Faculty of Pharmacy, University of Medical Sciences, Attar Neishaboori st., Golgasht st.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Fax
+98 41 3334 4798

Email
valizadehh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parviz Shahabi

Street address
No.2 Central Building 3rd Floor, University of Medical Sciences, Daneshgah st.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Fax
+98 41 3334 4798

Email
shahabip@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Tabriz University of Medical Sciences

Full name of responsible person
Hadi Valizadeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, University of Medical Sciences, Golgasht st Attar Neishaboori st. Tabriz University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
valizadehh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hadi Valizadeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, University of Medical Sciences,Golgasht st Attar Neishaboori st. Tabriz

University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
valizadehh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hadi Valizadeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, University of Medical Sciences, Golgasht st Attar Neishaboori st. Tabriz University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
valizadehh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable