

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### **In- Vivo Bioequivalence study of Mesalazine 500 mg EC tablet Faran shimi Pharma with brand drugs (Asacol® 400 mg ER. Tablets. Tillotts Pharma AG, Switzerland) in Iranian healthy volunteers.**

#### **Protocol summary**

##### **Study aim**

In- Vivo Bioequivalence study of Mesalazine 500 mg EC tablet Faran shimi Pharma with brand drugs (Asacol® 400 mg ER. Tablets. Tillotts Pharma AG, Switzerland) in Iranian healthy volunteers.

##### **Design**

In-vivo bioequivalence study of Mesalazine 500 mg EC tablet Faran shimi Pharma in comparison with reference drug (Asacol® 400 mg ER. Tablets. Tillotts Pharma AG, Switzerland). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

##### **Settings and conduct**

This study is carried out in Simin Baspar Tayf-Gostar Company, Tabriz, Iran. The study population is 24 healthy Iranian volunteers. This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 72 hours with a two-week wash-out period.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: age between 18-60 years old; body mass index (BMI) in the range of 18-28. Exclusion criteria: history of heart, kidney and liver disease; pregnancy; drug addiction

##### **Intervention groups**

Single dose Mesalazine 500 mg EC tablet Faran shimi Pharma. Control group: Single dose Asacol® 400 mg ER. Tablets. Tillotts Pharma AG, Switzerland

##### **Main outcome variables**

Plasma drug concentration

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20200105046010N63**

Registration date: **2022-06-26, 1401/04/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-06-26, 1401/04/05**

Update count: **0**

##### **Registration date**

2022-06-26, 1401/04/05

##### **Registrant information**

##### **Name**

Javad Shokri

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 41 3661 4125

##### **Email address**

shokri.j@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2022-06-26, 1401/04/05

##### **Expected recruitment end date**

2022-12-26, 1401/10/05

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

In- Vivo Bioequivalence study of Mesalazine 500 mg EC

tablet Faran shimi Pharma with brand drugs (Asacol® 400 mg ER. Tablets. Tillotts Pharma AG, Switzerland) in Iranian healthy volunteers.

#### Public title

In-vivo Bioequivalence Test of Mesalazine 500 mg EC tablet Faran shimi Pharma with brand drug (Asacol® 400 mg ER. Tablets. Tillotts Pharma AG, Switzerland)

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

General health Body mass index between 18-28 Informed consent Being at the age of 18-60 years old

##### Exclusion criteria:

Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

Bioequivalence

#### Groups that have been masked

- Care provider

#### Sample size

Target sample size: **24**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

For this purpose, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Candidates are not aware of receiving the test drug or brand one. In a single study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and Brand drugs are removed from their packaging by the executor and placed in similar and coded cans.

Volunteers will not be informed about receiving the brand or test drug.

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

#### Approval date

2021-11-29, 1400/09/08

#### Ethics committee reference number

IR.TBZMED.REC.1400.827

#### Health conditions studied

#### 1

#### Description of health condition studied

Bio equivalence test

#### ICD-10 code

#### ICD-10 code description

#### Primary outcomes

#### 1

#### Description

Plasma drug concentration

#### Timepoint

Sampling times in this study will be 0, 1, 2, 3.4, 6, 6.5, 7, 7.5, 8, 9, 10, 10.5, 11, 12 , 24 ,48 hours after prescribing the tablet.

#### Method of measurement

High Performance Liquid Chromatography with tandem mass spectroscopy detector

#### Secondary outcomes

empty

#### Intervention groups

#### 1

#### Description

One test tablet ( Mesalazine 500 mg EC tablet Faran shimi Pharma ) will be received. Blood samples will be taken for 24 hours at the mentioned times after drug administration and the concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector

#### Category

Treatment - Other

## 2

### Description

Control group: One Reference tablet Asacol® 400 mg ER. Tablets. Tillotts Pharma AG, Switzerland will be received. Blood samples will be taken for 48 hours at the mentioned times after drug administration and the concentration of drug in plasma samples will be measured by liquid chromatography with mass spectroscopy detector.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Simin Baspar Teyf Gostar Company

##### Full name of responsible person

Javad Shokri

##### Street address

No.48, Ferdos square

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167874434

##### Phone

+98 41 3384 2724

##### Email

Shokri.j@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Pharan shimi Pharmaceutical Company

##### Full name of responsible person

Sahar Pedram

##### Street address

No. 3, Kaveh Dedend, Entezami St., Attar Square, Attar St, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

6583117698

##### Phone

+98 21 5794 1000

##### Email

info@faranshimi.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Pharan shimi 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

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Simin Baspar Teyf Gostar Company

##### Full name of responsible person

Dariush Omidfar

##### Position

Lab. Manager

##### Latest degree

Master

##### Other areas of specialty/work

Bioanalysis

##### Street address

No.48, Ferdos square

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167874434

##### Phone

+98 41 3384 2724

##### Email

Dariush.omidfar@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Javad Shokri

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166414766

**Phone**

+98 41 3334 8489

**Email**

Shokri.j@gmail.com

**Phone**

+98 41 3384 2724

**Email**

ahad.sheikhloo@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Simin Baspar Teyf Gostar Company

**Full name of responsible person**

Ahad Sheikhloo

**Position**

Official Manager

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

**Street address**

No.48, Ferdos square

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5167874434

## 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**

All information and data of the study will remain secured based on the agreement established between researcher and drug producer.

**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**

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