

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Bioequivalence study of Sirolimus 1mg manufactured by Alborz Zagros company versus originator brand in healthy volunteers in fasting condition

#### Protocol summary

##### Study aim

Bioequivalence Study of Sirolimus 1mg manufactured by Alborz Zagros company versus originator brand (Rapamune) manufactured by Pfizer company

##### Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

##### Settings and conduct

The study is a single-blinded, cross-over and fasting, and on two series of healthy volunteers. The study will be done in Tabriz, Simin bespar teyf gostar company in two periods (72h). The interval between these two periods is 3 weeks. In the first round of the study, the candidates divide into two groups and the first group receives a test tablet and the second group receives a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: General Health (Liver, Heart, and Kidney), Body Mass Index (18-28), Informed consent, Age (18-55 years old) Exclusion criteria: Smoking, History of cardiovascular disease, History of liver and kidney disease, Alcoholism and Narcoticism, History of allergy to ESirolimus

##### Intervention groups

Intervention group 1: Rapamune 1mg tablet as a reference Intervention group 2: Sirolimus 1mg manufactured by Alborz zagros as a test

##### Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration, Half-life of drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200623047902N11**  
Registration date: **2021-12-13, 1400/09/22**  
Registration timing: **prospective**

Last update: **2021-12-13, 1400/09/22**

Update count: **0**

##### Registration date

2021-12-13, 1400/09/22

##### Registrant information

##### Name

Elham Ghasemian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6696 5196

##### Email address

ghasemian@zistdaru.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-02, 1401/01/13

##### Expected recruitment end date

2022-06-21, 1401/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Bioequivalence study of Sirolimus 1mg manufactured by

Alborz Zagros company versus originator brand in healthy volunteers in fasting condition

#### Public title

Bioequivalence study of Sirolimus 1mg tablet

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)

##### Exclusion criteria:

Smoking History of cardiovascular disease History of liver and kidney disease Alcoholism and Narcoticism History of allergy to Sirolimus

#### Age

From **18 years** old to **55 years** old

#### Gender

Both

#### Phase

Bioequivalence

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **24**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball and poured into a container and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: Alborz Zagros's medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

This study is a single-blinded clinical trial (volunteers). Alborz Zagros's Sirolimus and Originator brand's tablets 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 dosage form

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

### Secondary Ids

empty

### Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Tabriz University of Medical Sciences

##### Street address

No.58, 8th St. Kooye Nasr (Gisha St.)

##### City

Tehran

##### Province

Tehran

##### Postal code

1446863914

#### Approval date

2021-11-29, 1400/09/08

#### Ethics committee reference number

IR.TBZMED.REC.1400.830

### Health conditions studied

### 1

#### Description of health condition studied

This study is performed on healthy volunteers and drug concentration in whole blood is determined.

#### ICD-10 code

#### ICD-10 code description

### Primary outcomes

### 1

#### Description

Drug concentration in blood

#### Timepoint

0; 0.33, 0.66; 1; 1.33; 1.66, 2; 3; 4; 6; 8; 10; 12; 24; 48; 72h after drug administration

#### Method of measurement

Liquid chromatography-MASS-MASS (LC- Mas/Mas

### Secondary outcomes

### 1

#### Description

Time to reach maximum blood concentration

#### Timepoint

After intervention

#### Method of measurement

Time to reach the maximum drug concentration is recorded.

### 2

#### Description

Extent of absorption

#### Timepoint

After intervention

#### Method of measurement

Calculation of area under curve of concentration -time

## Intervention groups

### 1

#### Description

Intervention group: single dose, 3 oral tablet 1mg (Rapamune) manufactured by Pfizer, as a reference product

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Single dose, 3 oral Sirolimus 1mg tablet manufactured by Alborz Zagros company as test product

#### Category

Treatment - Drugs

## 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 Street

##### 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

Alborz Zagros company

##### Full name of responsible person

Amir Hossein Zolfaghari

##### Street address

No.58, 8th St. Kooye Nasr (Gisha St.)

##### City

Tehran

##### Province

Tehran

##### Postal code

1446863914

##### Phone

+98 21 4163 7000

##### Email

A.zolfaghari@alborzzagros.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Alborz Zagros 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

Islamic Azad University

##### Full name of responsible person

Elham Ghasemian

##### Position

Visiting professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

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##### Phone

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##### Email

Ghasemian\_elham@yahoo.com

## Person responsible for scientific inquiries

#### Contact

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Islamic Azad University

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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**City**

Tehran

**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**

These data are secure between researchers and related industries.

**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