Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Bioequivalence study of Sirolimus 1mg manufactured by Zist takhmir company versus originator brand in healthy volunteers in fasting condition

Protocol summary

Study aim
Bioequivalence Study of Sirolimus 1mg manufactured by Zist takhmir 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, in Radin laboratory in two (72h) periods. 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 Sirolimus

Intervention groups
Intervention group 1: Rapamune 1mg tablet as a reference Intervention group 2: Sirolimus 1mg manufactured by Zist takhmir 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: **IRCT20200623047902N35**
Registration date: **2023-05-10, 1402/02/20**
Registration timing: **prospective**

Last update: **2023-05-10, 1402/02/20**
Update count: **0**

Registration date
2023-05-10, 1402/02/20

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
2023-06-20, 1402/03/30

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence study of Sirolimus 1mg manufactured by

Zist takhmir 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: Zist takhmir'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). Zist takhmir'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
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2023-04-17, 1402/01/28
Ethics committee reference number
IR.TBZMED.REC.1402.089

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 drug concentration in blood
Timepoint
After intervention
Method of measurement
Time to reach the maximum drug concentration is recorded.

2

Description
Extent of drug 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 Zist takhmir company as a test product
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin laboratory
Full name of responsible person
Javad Shokri
Street address
No.22, first floor, Moalem st., Abureihan St
City
Tabriz
Province
East Azarbaijan
Postal code
5154995671
Phone
+98 914 313 5843
Email
Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zist takhmir company
Full name of responsible person
Sahar Bahmani
Street address
No. 597, Heydarkhani 4 way, Farjam Street, Resalat Square
City
Tehran
Province
Tehran
Postal code
1683848411
Phone
+98 21 7713 2961
Email
info@zisttakhmir.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zist takhmir 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
Street address
Faculty of Pharmacy, Islamic Azad university of Damghan, Cheshme Ali bolivar, Saadi square
City
Damghan
Province
Semnan
Postal code
3671637856
Phone
+98 23 3522 5046
Fax
Email
Ghasemian_elham@yahoo.com

Person responsible for scientific inquiries

Contact
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Ghasemian_elham@yahoo.com

Person responsible for updating data

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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 as 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