Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

In- Vivo Bioequivalence study of Everolimus tablet 10 & 0.75 mg SOBHAN ONCOLOGY (Everolimus 10mg) with brand drug (AFINITOR® 10mg Novartis) in Iranian healthy volunteers

Protocol summary

Study aim
In- Vivo Bioequivalence study of Everolimus tablet 10 & 0.75 mg SOBHAN ONCOLOGY (Everolimus 10mg) with brand drug (AFINITOR® 10mg Novartis) in Iranian healthy volunteers

Design
In-vivo bioequivalence study of test (Everolimus tablet 10 & 0.75 mg SOBHAN ONCOLOGY, IRAN) in compared with reference drug (AFINITOR® 10mg Novartis, 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 period.

Settings and conduct
This study will carried out in Simin Baspar Tayf Gostar Company, Tabriz, Iran. The number of participant is 24 healthy Iranian volunteers. This study is single blind by taking the drugs out of their original packaging, the volunteers will not know the The types of receiving drugs (test or brand). This study is a cross over, two periods, two times (each times is 72 hours) with a one-week wash-out period.

Participants/Inclusion and exclusion criteria
Inclusion criteria: participants are between 18-60 years old, Normal body mass index (BMI in the range of 18-28). Exclusion criteria: smoking, History of heart, kidney or liver disease, Pregnancy, Drug addiction

Intervention groups
Single dose Everolimus tablet 10 & 0.75 mg SOBHAN ONCOLOGY Pharmaceuticals. Control group: brand drugs (AFINITOR® 10mg Novartis, Switzerland)

Main outcome variables
Determination of blood drug concentration.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N44**
Registration date: **2021-11-15, 1400/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-15, 1400/08/24**
Update count: **0**

Registration date
2021-11-15, 1400/08/24

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
2021-11-11, 1400/08/20

Expected recruitment end date
2022-08-11, 1401/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Everolimus tablet 10 &

0.75 mg SOBHAN ONCOLOGY (Everolimus 10mg) with brand drug (AFINITOR® 10mg Novartis) in Iranian healthy volunteers

Public title
In-vivo Bioequivalence Test of Everolimus tablet with brand drugs (AFINITOR® 10mg Novartis).

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General health Body mass index between18-28 Informed consent Being at the age of 18-60 years old

Exclusion criteria:
Smoking History of cardiovascular disease History of liver or kidney disease Pregnancy Alcohol & Drug addiction History of hypersensitivity

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

Gender
Male

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
13 plasma samples in each period with distinct time intervals for each subject

Randomization (investigator's opinion)
Randomized

Randomization description
For this reason, A 24- person group will be selected and divided to two 12-person 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 one-blind 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 drug (Everolimus tablets) are withdrawal from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about the types of receiving drugs (test or brand).

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, 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
2021-08-02, 1400/05/11

Ethics committee reference number
IR.TBZMED.REC.1400.468

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. Subject bio equivalence test and reference tablets Everolimus studied.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determination of blood drug concentration.

Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.

Method of measurement
High Performance Liquid Chromatography tandem mass spectroscopy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: they will receive one test drug (Everolimus 10 or 0.75 mg Tablets SOBHAN ONCOLOGY. Iran). Blood samples will be taken during 72 hours at the mentioned times after drug administration and the concentration of Everolimus in blood samples will be measured by liquid chromatography- Tandem mass

spectroscopy method.

Category

Treatment - Other

2

Description

Control group: Control group: will receive one test drug (AFINITOR® 10 or 0.75 mg Novartis Switzerland). Blood samples will be taken from the volunteers during 72 hours at the mentioned times after drug administration and the concentration of Everolimus in blood samples will be measured by High performance liquid chromatography- Tandem mass spectroscopy method.

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 3693 4125

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

SOBHAN ONCOLOGY Pharmaceutical CO.

Full name of responsible person

Mitra Hajarian

Street address

No. 11, 5th Alley, Bucharest Ave,Argentina Sq, Tehran

City

Tehran

Province

Tehran

Postal code

7636318451

Phone

+98 21 8848 0161

Email

info@sobhanpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

SOBHAN ONCOLOGY Pharmaceutical CO.

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

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Full Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

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East Azarbaijan

Postal code

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Phone

+98 41 3334 8489

Email

Shokri.j@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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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 date are as secure between researcher 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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable

When the data will become available and for how long

Only protocol and methods of study are shareable.

To whom data/document is available

Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document

This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

Comments