Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

In- Vivo Bioequivalence study of Everolimus tablet 10mg ABIDI (NEORAPA® 10mg) with brand drug (AFINITOR® 10mg Novartis) in Iranian healthy volunteers.

Protocol summary

Study aim
In- Vivo Bioequivalence study of Everolimus 10mg ABIDI with brand drugs (AFINITOR® 10mg Novartis).

Design
Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct
This study will be conducted in one-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours.The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria
24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-28 respectively

Intervention groups
Intervention group Single dose NEORAPA® 10mg ABIDI Pharmaceutical Company with brand drugs (AFINITOR® 10mg Novartis)

Main outcome variables
Determination of blood drug concentration.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N24**
Registration date: **2021-02-23, 1399/12/05**
Registration timing: **prospective**

Last update: **2021-02-23, 1399/12/05**
Update count: **0**

Registration date
2021-02-23, 1399/12/05

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
2021-05-31, 1400/03/10

Expected recruitment end date
2022-03-01, 1400/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Everolimus tablet 10mg ABIDI (NEORAPA® 10mg) with brand drug (AFINITOR® 10mg Novartis) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence Test of NEORAPA® tablet with brand drugs (AFINITOR® 10mg Novartis).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health Body mass index(18-28) Informed consent Age(18-60)
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

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation law will be used for randomization of volunteers in this study. This method represents a large block for the total sample size, which means that a balance in the number of people assigned to each group will be obtained at the end of the study. By this method, sequences 1(subjects no: 1-12) and sequences 2 (subjects no: 13-12) will be selected by using a simple paper lottery. the first and second 12 persons will be considered as sequence 1 (Group A) and sequence 2 (Group B) respectively.
Blinding (investigator's opinion)
Single blinded
Blinding description
Candidates are not aware of the test drug or brand name. 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. Tramadol and Tramadol 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
Ethics Committee, Tabriz University of Medical Sciences
Street address
Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-02-08, 1399/11/20
Ethics committee reference number
IR.TBZMED.REC.1399.1049

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. Subject bioequivalence 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
igh Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group received one test drug table(Everolimus tablet 10mg ABIDI Pharmaceutical Company). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Everolimus in blood samples was measured by liquid

chromatography with mass spectroscopy detector.

Category

Treatment - Drugs

2

Description

Control group: Control group received one test drug table (AFINITOR® 10mg Novartis). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of AFINITOR in blood samples was measured by liquid chromatography with mass spectroscopy detector.

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

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5167874434

Phone

+98 41 3384 2724

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ABIDI Pharmaceutical Company

Full name of responsible person

Amir Razavian

Street address

No. 72, Abidi Boulevard, 8 km of Shahid Lashkari Highway, Tehran

City

Tehran

Province

Tehran

Postal code

7636313897

Phone

+98 21 4452 2451

Email

info@abidi-diabetes.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Tabriz University of Medical Sciences

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

Other

Person responsible for general 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

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Faculty of Pharmacy, Tabriz University of Medical Sciences.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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 sharable.

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