Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

In- Vivo Bioequivalence study of Everolimus tablet 0.75 mg Nano-Alvand (ROLIMA® 0.75 mg) with brand drug (CERTICAN® 0.75 mg, Novartis,Switzerland) in Iranian healthy volunteers

Protocol summary

Study aim
In- Vivo Bioequivalence study of Everolimus tablet 0.75 mg Nano-Alvand (ROLIMA® 0.75 mg) with brand drug (CERTICAN® 0.75 mg, Novartis,Switzerland) in Iranian healthy volunteers

Design
In-vivo bioequivalence study of test (Everolimus tablet 0.75 mg Nano-Alvand, IRAN) in compared with reference drug (CERTICAN® 0.75 mg, Novartis, Switzerland). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method).

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: age between 18-55 years old; body mass index (BMI) in the range of 18-28. Exclusion criteria: history of heart, kidney and liver disease; pregnancy; drug addiction; smoking

Intervention groups
Single dose Everolimus tablet 0.75 mg Nano-Alvand Pharmaceuticals. Control group: brand drugs (CERTICAN® 0.75 mg, Novartis, Switzerland)

Main outcome variables
Determination of blood drug concentration.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N58**
Registration date: **2022-04-09, 1401/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-09, 1401/01/20**
Update count: **0**

Registration date
2022-04-09, 1401/01/20

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
2022-03-27, 1401/01/07

Expected recruitment end date
2022-12-01, 1401/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Everolimus tablet 0.75 mg Nano-Alvand (ROLIMA® 0.75 mg) with brand drug

(CERTICAN® 0.75 mg, Novartis,Switzerland) in Iranian healthy volunteers

Public title
In-vivo Bioequivalence Test of Everolimus tablet (ROLIMA® 0.75 mg) with brand drugs (CERTICAN® 0.75 mg, Novartis,Switzerlan)
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
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
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
2022-01-12, 1400/10/22
Ethics committee reference number
IR.TBZMED.REC.1400.1044

Health conditions studied

1

Description of health condition 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 0.75 mg Tablets Nano-Alvand). 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: will receive one test drug (CERTICAN® 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nanoalvand Pharmaceutical Co.

Full name of responsible person
Saeed Shahbazi

Street address
No. 485, Unit 52, between 63 and 65th Street, Iran, Yousefabad,Tehran

City
Tehran

Province
Tehran

Postal code
5167874434

Phone
+98 21 8802 0579

Email
info@nanoalvand.com

Web page address
http://nanoalvand.com

Grant name

Grant code / Reference number

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

Title of funding source
Nanoalvand 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
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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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