Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 2026

In- Vivo Bioequivalence study of Tofacitinib tablet 10 mg Nano Alvand Pharma (RHOFANIB®) with brand drugs (XELJANZ® 10 mg, Pfizer, Ireland) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Tofacitinib tablet 10 mg Nano Alvand Pharma (RHOFANIB®) with brand drugs (XELJANZ® 10 mg, Pfizer, Ireland) in Iranian healthy volunteers.

Design

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

Settings and conduct

This study will be conducted in single-dose, 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 similar tablets. Blood samples will be 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 dysfunctions with both sexes (male&female). The ages and BMIs of the participants should be in the range of 18-60 and 18-28 respectively

Intervention groups

Single dose Tofacitinib tablet 10 mg Nano Alvand Pharma Company with brand drugs (XELJANZ® 10 mg, Pfizer, Ireland)

Main outcome variables

Determination of blood drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N38**
Registration date: **2021-09-04, 1400/06/13**
Registration timing: **prospective**

Last update: **2021-09-04, 1400/06/13**
Update count: **0**

Registration date

2021-09-04, 1400/06/13

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

2021-09-06, 1400/06/15

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Tofacitinib tablet 10 mg Nano Alvand Pharma (RHOFANIB®) with brand drugs (XELJANZ® 10 mg, Pfizer, Ireland) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence study of Rhofinib tablet with brand drugs (XELJANZ® 10 mg, Pfizer, Ireland)

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
For this purpose, first determine a total sample size (24 people), then write the names of the people on paper, and after folding in aluminum foil, pour it into a glass, and then randomly remove the papers and open the first 12 people in group A and The rest are selected as group B.

Blinding (investigator's opinion)
Single blinded

Blinding description
Iranian Tofacitinib tablet and Tofacitinib brand 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 medications

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
2021-08-02, 1400/05/11

Ethics committee reference number
IR.TBZMED.REC.1400.466

Health conditions studied

1

Description of health condition studied
Bio equivalence test

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 with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: will receive one test drug tablet (Tofacitinib tablet 10 mg Nano Alvand Pharma). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Tofacitinib in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category
Treatment - Other

2

Description
Control group:will receive one test drug table (XELJANZ® 10 mg, Pfizer, Ireland). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Tofacitinib in blood samples will be measured by liquid chromatography with mass spectroscopy detector

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 Street

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Tabriz

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5167874434

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+98 41 3384 2724

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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nanoalvand Pharmaceutical Co

Full name of responsible person
saeed shahbazi

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

City
Tehran

Province
Tehran

Postal code
66469122

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

Street address
Faculty of Pharmacy, University of Medical Sciences, Daneshgah Street,Tabriz East Azerbayjan

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Person responsible for scientific inquiries

Contact

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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. Information will be provided to the applicant upon request by the contractor via email after the employer agrees.

Comments