Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Bioequivalence study of Tofacitinib 10 mg tablet manufactured by Cobel daru versus originator brand in healthy volunteers in the fasted condition

Protocol summary

Study aim
Bioequivalence Study of Tofacitinib 10 mg (Alpamon)manufactured by Cobel daru company versus originator brand (Xeljanz) 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 two periods (24h). The interval between these two periods is one week. In the first round of the study, the candidates divide into two groups. 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. These steps are performed in Radin Laboratory in Tabriz.

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; alcohol and drug addiction; history of allergy to Tofacitinib.

Intervention groups
Intervention group 1: single dose, one oral tablet 10 mg (Xeljanz) manufactured by Pfizer company, as a reference product Intervention group 2: single dose, one oral tablet 10 mg (Alpamon) manufactured by Cobel daru company as a test. the washout period is one week. in the second sequence of sampling, the volunteers that consumed the test drug will consume the reference drug and vice versa.

Main outcome variables
drug concentration, Time to reach maximum drug concentration, extent of absorption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N79**
Registration date: **2023-07-11, 1402/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-11, 1402/04/20**
Update count: **0**

Registration date
2023-07-11, 1402/04/20

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
2023-06-22, 1402/04/01

Expected recruitment end date
2024-03-18, 1402/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Bioequivalence study of Tofacitinib 10 mg tablet manufactured by Cobel daru versus originator brand in healthy volunteers in the fasted condition

Public title
Bioequivalence study of Tofacitinib 10 mg 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 alcohol and drug addiction history of allergy to Tofacitinib
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**
More than 1 sample in each individual
Number of samples in each individual: **30**
Blood sample
Randomization (investigator's opinion)
Randomized
Randomization description
Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container and divided into 2 groups of 12 test (A) and reference (B) drug recipients, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blinded clinical trial (volunteers). Cobel daru's Tofacitinib and Originator brand capsules 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
Tabriz University of Medical Sciences ethics committe
Street address
3th Floor, Research and Technology Vice-Chancellor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2023-05-29, 1402/03/08
Ethics committee reference number
IR.TBZMED.REC.1402.185

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The concentration of the drug in blood
Timepoint
Pre-dose, 0.25, 0.5, 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, and 24 h after drug administration
Method of measurement
Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description
Time to reach maximum blood concentration
Timepoint
After intervention
Method of measurement
Clock

2

Description
Extent of absorption
Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group 1: single dose, one oral tablet 10 mg (Xeljanz) manufactured by Pfizer company, as a reference product
Category
Treatment - Drugs

2

Description
Intervention group 2: Single dose, one oral Alpamon 10 mg tablet manufactured by Cobel daru company as a test product. The washout period is one week. in the second sequence of sampling, the volunteers that consumed the test drug will consume the reference drug and vice versa.
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
Fax
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
Street address
3rd floor of Research and Technology Vice-Chancellor, No 2 Central Building, Tabriz University of Medical Sciences, University Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3334 1249
Fax
+98 21 8867 1240
Email
research-vice @tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

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
No 4, 10th Ave. Boostan Street, Roshdieh, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5155935357
Phone
+98 41 3661 4125
Fax
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
Javad Shokri
Position

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Person responsible for updating data

Contact

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Tabriz University of Medical Sciences

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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