

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 committee

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

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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 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