

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Fasted-state in vivo bioequivalence study of Celecoxib 100 mg tablet manufactured by Farnoush Daru Teb Co. compared with innovator product

Protocol summary

Study aim

Investigating bioequivalence of Celecoxib tablet compared to innovator product

Design

This randomized clinical trial with a control group will be conducted in a cross-over, open-label; on 24 healthy volunteers. A lottery method will be used for randomization.

Settings and conduct

After administration of one 100mg tablet to volunteer, the blood samples will be collected in predetermined time intervals up to 48 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. the study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences. This trial will be conducted in an open-label fashion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart, and Kidney); Age (18-60 years old). Exclusion criteria: Smoking; history of cardiovascular; liver and kidney disease; pregnancy; alcohol and drug addiction; history of drug allergy.

Intervention groups

Intervention group will receive one test drug product. Blood samples will be taken from the volunteers for 48 hours at the mentioned time points after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. Control group will receive one reference drug product. Blood samples will be taken from the volunteers for 48 hours at the mentioned time points after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector.

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051345N15**

Registration date: **2022-08-17, 1401/05/26**

Registration timing: **prospective**

Last update: **2022-08-17, 1401/05/26**

Update count: **0**

Registration date

2022-08-17, 1401/05/26

Registrant information

Name

Parvin Zakeri-Milani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

pzakeri@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-16, 1401/06/25

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Fasted-state in vivo bioequivalence study of Celecoxib 100 mg tablet manufactured by Farnoush Daru Teb Co. compared with innovator product

Public title

Investigating the in vivo bioequivalence of Celecoxib 100 mg tablet

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

General Health (in terms of Liver, Heart and Kidney)

Exclusion criteria:

Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Biomedical Research Committee, Tabriz University of Medical Sciences

Street address

No.2 Central Building 3rd Floor, University of Medical Sciences, Daneshgah st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2022-08-01, 1401/05/10

Ethics committee reference number

IR.TBZMED.REC.1401.402

Health conditions studied**1****Description of health condition studied**

In the present study, the products will be administered to healthy volunteers.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma concentration of drug

Timepoint

0.5-48 hours in predetermined time intervals after drug administration (0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 12, 24, 48 h)

Method of measurement

HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group will receive a single test drug product. Blood samples will be collected for 48 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector

Category

Treatment - Drugs

2**Description**

Control group: Control group will receive a single reference drug product. Blood samples will be collected for 48 hours at the mentioned times after drug administration and the concentration of drug in blood

samples will be measured by liquid chromatography equipped with mass spectroscopy detector.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences, Faculty of Pharmacy

Full name of responsible person

Parvin Zakeri-Milani

Street address

Faculty of Pharmacy, University of Medical Sciences, Golgasht st., Attar Neishaboori st.

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Phone

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Email

pzakeri@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

No.2 Central Building 3rd Floor, Daneshgah st. Tabriz University of Medical Science

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shahabip@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Farnoosh Darou Teb Pharmaceutical Company

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, University of Medical Sciences, Golgasht st., Attar Neishaboori st.

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable