

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Celecoxib 200 mg capsules produced by Daana pharmaceutical Co versus Celebrex® (Pfizer company) in 24 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Dana Celecoxib 200 mg capsules versus Celebrex® (Pfizer Co.)

Design

Single dose, randomized and crossover bioequivalence study of Celecoxib 200 mg capsules by Dana Co. with Celebrex® (Pfizer Co.) in 24 healthy male in two groups under fasting condition.

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for Blood and plasma sample analysis: Imam Reza Medical Research and Training Hospital. 24 healthy male volunteers received each of two test or reference Celecoxib 200 mg tablets in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before receiving the drug and 48 hours after that at determined time points: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24 and 48 hours.

Participants/Inclusion and exclusion criteria

Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 140/90 mm/Hg Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma, DM, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group (Test): Celecoxib 200 mg capsules by Dana Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. Control group (Reference): Celebrex® (Pfizer Co.) is the

reference product. In each period, 12 of 24 subjects will be given single dose of this product.

Main outcome variables

Peak Plasma Concentration (C_{max}); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N11**

Registration date: **2021-06-23, 1400/04/02**

Registration timing: **prospective**

Last update: **2021-06-23, 1400/04/02**

Update count: **0**

Registration date

2021-06-23, 1400/04/02

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-21, 1400/04/30

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, single-dose, crossover comparative bioequivalence study of the Celecoxib 200 mg capsules produced by Daana pharmaceutical Co versus Celebrex® (Pfizer company) in 24 healthy males under fasting conditions

Public title

Study of absorption and elimination rate of Celecoxib 200 mg capsules in comparison with standard capsules of Celecoxib (Celebrex®).

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

The weight limit for each volunteer is between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Celecoxib or any ingredients. Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two week before dosing.

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **28**

In each period, 14 blood samples are collected from each subject and this study includes 2 periods.

Randomization (investigator's opinion)

Randomized

Randomization description

First, a table of random numbers from 1 to 24 is created. The table numbers are assigned to individuals in the order in which the candidates enter the list on the day of the experiment, and the candidates in two groups with numbers 1-12 and numbers 13-24 will receive reference and test medicine, respectively.

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**

Ethics committee of Tabriz University of Medical Science

Street address

Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran

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Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.TBZMED.REC.1400.252

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

analgesic and anti inflammation

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

Peak Plasma Concentration (Cmax)

Timepoint

At 0 (before dosing), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24 and 48 hour after dosing

Method of measurement

High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes**1****Description**

AUC (Area Under the Concentration-Time Curve)

Timepoint

During 2 months after intervention

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description

Intervention group (Test): Celecoxib 200 mg capsules, produced by Daana Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. In the second period, after washout, this group (test) will be in the reference group and will use brand drug (Celebrex, 200 mg).

Category

Treatment - Drugs

2

Description

Intervention group (Reference): Celecoxib 200 mg capsules (Celebrex), produced by Pfizer Company is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. In the second period, after washout, this group (Reference) will be in the test group and will use domestic Celecoxib 200 mg capsules.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center

Full name of responsible person

Dr Hamed Hamishehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Daana pharmaceutical company

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Daana 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

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

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Latest degree

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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

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