Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Bioequivalence Study of sustained release Diclofenac 100 mg capsule manufactured by Tasinm Pharmaceutical and and Diclofenac 100 mg capsule menufactured by Ratio pharm in 24 Healthy volunteers under fasting condition

Protocol summary

Study aim

Comparison of the bioavailability of Diclofenac sustained release capsules after a single dose of 100 mg, manufactured by Tasnim Pharmaceutical and Ratio pharm.

Design

The study is a cross-over double-blind study. 24 healthy volunteers using the random option in excel software will be assigned a code, and depending on the code, the first half will receive the test, and the second half will receive reference drugs. In each phase of the study, 12 blood samples will be received from the individual.

Settings and conduct

On the day of sampling, after 10 hours of fasting, the volunteers come to Kharazmi Plasma Center in Islamshahr (No. 13, 1st Shehamat Alley, Ali Ibn Abitalib St., Namaz Square,) and receive one capsule of the test or reference drug with 240 ml of water and blood samples are taken at 0, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 24 hours after drug administration, after plasma separation, the samples were transferred to a -70 freezer and finally the concentration of drug in plasma will be determined according to the LCMSMS method.After a one-week wash out period, the process of drug administration is done vise versa.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy adult male (18 - 55 yrs) and sterile or post menopausal female subjects, Body weight must be ≥50 kg and <100 kg, with a body mass index (BMI) >18 but <33.Laboratory parameter values must fall within the normal range Exclusion criteria: history of allergic reaction to Diclofenac . Smokers or user of tobacco products.

Intervention groups

Comparing the blood concentration of Diclofenac of Tasnim Pharmaceutical and Ratio pharm.

Main outcome variables

Plasma concentration caused by test and reference drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220209053979N12**
Registration date: **2023-12-07, 1402/09/16**
Registration timing: **prospective**

Last update: **2023-12-07, 1402/09/16**
Update count: **0**

Registration date

2023-12-07, 1402/09/16

Registrant information

Name

Roya Talari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8880 0892

Email address

talari_r@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2023-12-28, 1402/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence Study of sustained release Diclofenac 100 mg capsule manufactured by Tasinm Pharmaceutical and and Diclofenac 100 mg capsule menufactured by Ratio pharm in 24 Healthy volunteers under fasting condition

Public title

Bioequivalence of sustained release Diclofenac 100 mg capsule manufactured by Tasinm Pharmaceutical and Diclofenac 100 mg capsule manufactured by Ratio pharm

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy male or female volunteers Body mass index (BMI) between 18 - 30 Volunteers who are willing to sign an informed consent form

Exclusion criteria:

History of allergic reaction to memantin or formulation components Taking any type of medicine in the 14 days before the start of the study Participation in any type of clinical study in the last month

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **12**

5 mililitr blood sample is taken from each volunteers

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug (test or reference drug) is removed from the original packaging the day before the study and packaged in small disposable containers. Therefore, it is not in the original packaging and also the visual appearance and size of the test and reference capsules are the same , none of the volunteer nor the prescriber know which drug is being administered. The relevant code is also written on the sample collecting tubes of each volunteer, neither the analyzer knows the test or reference drug sample is analyzing.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Science

Street address

Tehran University of Medical Science, 16 Azar St.,

City

Tehran

Province

Tehran

Postal code

1417713135

Approval date

2023-11-26, 1402/09/05

Ethics committee reference number

IR. TUMS. TIPS. REC. 1402. 11

Health conditions studied

1

Description of health condition studied

A crossover bioequivalence study in 24 healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration time profile, maximum plasma concentration, AUC

Timepoint

0 ، 1، 1.5 ، 2 ، 2.5 ، 3، 4، 5، 6 ، 8، 10, 24 h after drug administration.

Method of measurement

Liquid chromatography with mass spectrophotometry

Secondary outcomes

1

Description

Calculation of pharmacokinetic parameters like Cmax, AUC of test and reference drug.

Timepoint

Same as primary outcome.

Method of measurement

Pharmacokientic parameters are calculated by excel.

Intervention groups

1

Description

Intervention group: Oral administration of one Diclofenac 100 mg capsule manufactured by Tasnim Pharmaceutical to 12 healthy volunteers under fasting condition with 240 ml of water. Then 12 blood samples are taken from volunteers at 0, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 24 hours after drug administration. In the second phase after a wash out period of one week , this group will take Ratio pharm medicine and blood samples are taken at the same times.

Category

Other

2

Description

Intervention group: Oral administration of one Diclofenac 100 mg capsule manufactured by Ratio pharm to 12 healthy volunteers under fasting condition with 240 ml of water. Then 12 blood samples are taken from volunteers at 0, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 24 hours after drug administration. In the second phase after a wash out period of one week , this group take Tasnim Pharmaceutical medicine and blood samples are taken at the same times.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kharazmi plasma center

Full name of responsible person

Sara Solgi

Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

City

Islamshahr

Province

Tehran

Postal code

3313679886

Phone

+98 21 5669 4726

Email

Info@kpcir.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tasnim Pharmaceutical

Full name of responsible person

Dr. Nami Moghadam

Street address

Tasnim Building, No. 3, 14th East Street, Beyhaqi St., Argentina Square

City

Tehran

Province

Tehran

Postal code

1517615814

Phone

+98 21 8877 2072

Email

info@tasnimpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tasnim Pharmaceutical

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

Kharazmi Plasma Center

Full name of responsible person

Roya Talari

Position

Executer

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

City

Islamshar

Province

Tehran

Postal code

3313679886

Phone

+98 21 5669 4726

Email
talari_r@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kharazmi Plasma Center
Full name of responsible person
Roya Talari
Position
Executer
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,
City
Islamshar
Province
Tehran
Postal code
3313679886
Phone
+98 21 5669 4726
Email
talari_r@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kharazmi Plasma Center
Full name of responsible person
Roya Talari
Position
Executer
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,
City
Islamshar
Province
Tehran
Postal code
3313679886
Phone
+98 21 5669 4726
Email
talari_r@yahoo.com

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
The bioequivalence study data is completely confidential and according to the contract with Tasnim Pharmaceutical Company, it should not be published anywhere.
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