Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Bioequivalence study of Mexiletine 200 mg capsule manufactured by Tadbir Kalaye Jam company in comparison with Mexiletine® 200 mg capsule ANNORA PHARMA PRIVATE LTD on healthy volunteers

Protocol summary

Study aim

Bioequivalence study of two Mexiletine 200 mg capsule manufactured by Tadbir Kalaye Jam company

Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers, Two period, Simple randomization method will be used.

Settings and conduct

This study will be conducted in two-way, Two period (48 hr with 1 week washout time), Single blinded, cross-over and fasting, and on two sets of healthy volunteers. In the first round, candidates are divided into two sequence using randomization software. The first sequence (even numbers) receives a reference tablet and the second sequence (odd numbers) receives a similar tablet of the test. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them. Plasma concentration data will be analyzed by WinNonLin software. The study will be done in Radin Shimi Co.

Participants/Inclusion and exclusion criteria

Inclusion criteria: non-smoking, not pregnant, no history of heart, kidney and liver disease or disfunctions. The ages and BMIs of participant should be in the range of 18-55 and 18-30 respectively. Exclusion criteria: Smoking, History of cardiovascular, liver and kidney disease; Alcohol and drug addiction, History of allergy to drug.

Intervention groups

Both groups received in cross-over design medication and testing at two different cross-sections and Therefor, the test results are independent of individual differences and it will only show the difference in the formulation of the two drugs.

Main outcome variables

Maximum concentration (Cmax), Time to reach maximum concentration (Tmax), Half life (T1/2), Elimination constant (Ke)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240803062623N12**
Registration date: **2025-02-21, 1403/12/03**
Registration timing: **prospective**

Last update: **2025-02-21, 1403/12/03**
Update count: **0**

Registration date

2025-02-21, 1403/12/03

Registrant information

Name

Mohammad Ali Karkhaneh Yousefi

Name of organization / entity

Tadbir Kalaye Jam co.

Country

Iran (Islamic Republic of)

Phone

+98 21 8866 8700

Email address

yousefi@tadbirkala.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-03-21, 1404/01/01

Expected recruitment end date

2027-09-23, 1406/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Mexiletine 200 mg capsule manufactured by Tadbir Kalaye Jam company in comparison with Mexiletine® 200 mg capsule ANNORA PHARMA PRIVATE LTD on healthy volunteers

Public title

Bioequivalence study of two Mexiletine 200 mg capsule manufactured by Tadbir Kalaye Jam company

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age (18-55years old) General Health (Liver, Heart, and Kidney) Body Mass Index (18-30) Informed consent

Exclusion criteria:

Smoking history of cardiovascular disease history of liver & kidney disease Alcohol & Drug addiction Hypersensitivity to the drug Pregnancy

Age

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

Gender

Both

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: **32**

Blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

People are checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24 using a randomization software. Even numbers will receive the reference and odd numbers will receive the test drug in the first period.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blinded clinical trial (volunteers). Test and Originator brand's tablets 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

Ethics committee of Tehran University of Medical Sciences

Street address

5th floor,No. 60, Mollasadra Ave, Vanak Sq

City

Tehran

Province

Tehran

Postal code

1435793175

Approval date

2025-01-21, 1403/11/02

Ethics committee reference number

IR.TUMS.TIPS.REC.1403.185

Health conditions studied

1

Description of health condition studied

In this study the , the disease is not investigated , bioequivalence of test and brand drug will be evaluated.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

0 , 0.5 , 1 , 1.5 , 2 , 2.5 , 3 , 3.5 , 4 , 5 , 6 , 8 , 10 , 12 , 24 , 48h after drug administration

Method of measurement

Liquid chromatography–mass spectrometry

Secondary outcomes

1

Description

Time to reach maximum plasma concentration

Timepoint

After intervention

Method of measurement

Time to reach the maximum drug concentration in plasma is recorded.

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: Single-dose of the test drug Mexiletine 200 mg capsule manufactured by Tadbir Kalaye Jam company

Category

Treatment - Drugs

2

Description

Control group: Single-dose of the reference drug Mexiletine® 200 mg capsule ANNORA PHARMA PRIVATE LTD in the first period.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Asr Nano company

Full name of responsible person

Mohammad Ali Karkhaneh Yousefi

Street address

Asr Nano company, Polymer research institute, Pajuhesh boulevard, Tehran

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+98 21 4478 7091

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yousefi@tadbirkala.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tadbir Kala Jam

Full name of responsible person

Mohammad Ali Karkhane Yosefi

Street address

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n.mohammadi@tadbirkala.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tadbir Kala Jam

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tadbir Kalaye Jam co.

Full name of responsible person

Mohammad Ali Karkhaneh Yousefi

Position

Medical Manager

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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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