

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Therefore, 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 (C_{max}), Time to reach maximum concentration (T_{max}), Half life (T_{1/2}), Elimination constant (K_e)

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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Sponsors / Funding sources

- 1**
Sponsor
Name of organization / entity
Tadbir Kala Jam
Full name of responsible person
Mohammad Ali Karkhaneh Yosefi
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5th floor, No.60, Mollasadra Ave. Vanak square
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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**
Name of organization / entity

Tadbir Kalaye Jam co.

Full name of responsible person

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Position

Medical Manager

Latest degree

Medical doctor

Other areas of specialty/work

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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