# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Fasted-state in vivo bioequivalence study of Mexiletine 200 mg capsule manufactured by Alborz Co. compared with innovator product

## Protocol summary

**Study aim**
In vivo bioequivalence study of Mexiletine 200 mg capsule

**Design**
The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy volunteers will participate randomly in the study as two twelve-person study groups. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation. Therefore, each volunteer will be his own "Control". To randomly assign participants in two groups, the lottery method will be used.

**Settings and conduct**
After oral administration of 200 mg capsule 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 concentration of drug in blood samples will be measured by liquid chromatography. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-59 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 a single oral dose of test drug product (Mexiletine 200 mg capsule manufactured by Alborz) and Control group will receive a single dose of reference drug product (Mexiletine 200 mg capsule manufactured in Canada). Blood samples will be taken for 48 hours at the mentioned time points after drug administration and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively.

**Main outcome variables**
Drug plasma concentration

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20210519051345N46**
Registration date: **2024-01-24, 1402/11/04**
Registration timing: **prospective**

Last update: **2024-01-24, 1402/11/04**
Update count: **0**

**Registration date**
2024-01-24, 1402/11/04

**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**
2024-02-04, 1402/11/15

**Expected recruitment end date**
2024-10-06, 1403/07/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Fasted-state in vivo bioequivalence study of Mexiletine 200 mg capsule manufactured by Alborz Co. compared with innovator product

**Public title**
Investigating Bioequivalence of Mexiletine 200 mg Capsule compared to innovator product

**Purpose**
Other

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
General Health (in terms of Liver, Heart and Kidney), Age (18-59 years)

**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**
Male

**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 Committe, Tabriz University of Medical Sciences

**Street address**
Biomedical Research Committe, Tabriz University of Medical Sciences

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
51664-14766

**Approval date**
2024-01-14, 1402/10/24

**Ethics committee reference number**
IR.TBZMED.REC.1402.776

## 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

**Method of measurement**
HPLC (High performance liquid chromatography)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Intervention group will receive a single oral dose of test product (Mexiletine 200 mg capsule manufactured by Alborz) in fasted state. 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 stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively

**Category**
Treatment - Drugs

### 2

**Description**
Control group: Control group will receive a single oral dose of reference product (Mexiletine 200 mg capsule

manufactured in Canada) in fasted state. 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 stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Faculty of Pharmacy, Tabriz University of Medical Sciences

**Full name of responsible person**
Parvin Zakeri-Milani

**Street address**
Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori St., Golgasht St.

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**Phone**
+98 41 3334 8801

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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, Tabriz University of Medical Sciences, Daneshgah St.

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**Email**
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**
Alborz 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, Tabriz University of Medical Sciences, Attar Neishaboori St., Golgasht St.

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
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**Position**
Professor

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## Person responsible for updating data

**Contact**
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Tabriz University of Medical Sciences
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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**
Not applicable
**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