

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Fasted-state in vivo bioequivalence study of Tinidazole 500 mg tablet

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Tinidazole 500 mg tablet

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male 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 one 500-mg tablet to volunteer, the blood samples will be collected in predetermined time intervals up to 72 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 equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old)

Intervention groups

Intervention group will receive a single oral dose of test drug product (Tinidazole 500 mg tablet manufactured by Kimia Ara Heram, Iran) and Control group will receive a single dose of reference drug product (Tinidazole 500 mg tablet manufactured by Fizer, India). Blood samples will be taken from the volunteers for 72 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: **IRCT20210519051345N17**

Registration date: **2022-10-12, 1401/07/20**

Registration timing: **prospective**

Last update: **2022-10-12, 1401/07/20**

Update count: **0**

Registration date

2022-10-12, 1401/07/20

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

2022-11-06, 1401/08/15

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Fasted-state in vivo bioequivalence study of Tinidazole
500 mg tablet

Public title

Bioequivalence study of Tinidazole 500 mg tablet

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

General Health (in terms of Liver, Heart and Kidney)

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

Both

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**

Ethics Committee of Biomedical Research, Tabriz
University of Medical Sciences

Street address

Faculty of Pharmacy, Tabriz University of Medical
Sciences, Golgasht st., Attar Neishaboori st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2022-10-03, 1401/07/11

Ethics committee reference number

IR.TBZMED.REC.1401.598

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

0.5-72 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 (Tinidazole 500 mg tablet
manufactured by Kimia Ara Heram Co., Iran) in fasted
state. Blood samples will be collected for 72 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 (Tinidazole 500 mg tablet
manufactured by Fizer, India) in fasted state. Blood
samples will be collected for 72 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, University of Medical Sciences, Golgasht st., Attar Neishaboori st.

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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, 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
Kimia Ara Heram Co.

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

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Faculty of Pharmacy, University of Medical Sciences, Golgasht st., Attar Neishaboori 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
Parvin Zakeri-Milani

Position
Professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

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