Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Bioequivalence study of Tolterodine 2 mg tablet compared with innovator product

Protocol summary

Study aim
In vivo bioequivalence study of Tolterodine 2 mg
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 2 mg tablet to volunteer, the blood samples will be collected in predetermined time intervals up to 12 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
General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old)
Intervention groups
Tolterodine tablets and brand medicine will be given to all people in a different order.
Main outcome variables
Drug plasma concentration

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210519051345N35**
Registration date: **2023-11-27, 1402/09/06**
Registration timing: **prospective**
Last update: **2023-11-27, 1402/09/06**
Update count: **0**
Registration date
2023-11-27, 1402/09/06

Registrant information
Name
Parvin Zakeri-Milani
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-01, 1402/09/10
Expected recruitment end date
2024-03-19, 1402/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence study of Tolterodine 2 mg tablet compared with innovator product

Public title
Bioequivalence study of Tolterodine 2 mg tablet
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

No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2023-11-20, 1402/08/29

Ethics committee reference number

IR.TBZMED.REC.1402.607

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

0.33-12 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 (Tolterodine 2 mg tablet manufactured by Hakim) in fasted state. Blood samples will be collected for 12 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 (Tolterodine 2 mg capsule manufactured in Germany) in fasted state. Blood samples will be collected for 12 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Hakim Pharmaceutical 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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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Professor

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Person responsible for updating data

Contact

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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