

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

In vivo bioequivalence study of Quetiapine 100 mg tablet manufactured by Fatak Shimi Co. in comparison to innovator product

Protocol summary

Study aim

Investigatin Bioequivalence of Quetiapine 100 mg tablet manufactured y Fatak Shimi Co. in compatison to innovator product

Design

Twenty-four healthy male volunteer will enter the study based on random numbers table as two groups of twelve people. 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 (without knowing the formulation identity in each period). Therefore, each volunteer will be his own "Control".

Settings and conduct

After administration of one 100 mg tablet to volunteer, the blood samples will be taken in predetermined time intervals up to 24 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. In this study the volunteer would not be aware of the formulation identity in each period

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (Liver, Heart and Kidney), Age (20-60) Exclusion criteria: Smoking, history of cardiovascular disease, history of liver and kidney disease, pregnancy, alcohol and drug addiction, history of drug allergy.

Intervention groups

Test group: Administrating the test product Control group: Administrating the innovator product In first period, one group of volunteers will receive single dose of Quetiapine 100 mg generic tablet (test formulation) and the second group will receive a single dose of the reference formulation of same drug. After one week wash out period, by cross over design, the first group and second group will administer the reference and test formulations, respectively.

Main outcome variables

Plasma concentration of drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051345N5**

Registration date: **2021-10-30, 1400/08/08**

Registration timing: **prospective**

Last update: **2021-10-30, 1400/08/08**

Update count: **0**

Registration date

2021-10-30, 1400/08/08

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

2021-11-16, 1400/08/25

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo bioequivalence study of Quetiapine 100 mg tablet manufactured by Fatak Shimi Co. in comparison to innovator product

Public title

Bioequivalence study of Quetiapine 100 mg tablet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: General Health (Liver, Heart and Kidney) Age (20-60)

Exclusion criteria:

Exclusion criteria: Smoking, history of cardiovascular disease, history of liver and kidney disease, pregnancy, alcohol and drug addiction history of drug allergy

Age

From **20 years** old to **59 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

"Random number table" will be used. Each volunteer will be assigned a two-digit number. After making the table, we need randomly point to a spot on the table and select the numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, Volunteers participating will be blinded to the type of product they are taking in each period (test or reference product). This means that the product will be given to the volunteers for administration outside the original packaging

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Research Committee, Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, No.2 Central

Building, 3rd Floor, Daneshgah st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2021-10-04, 1400/07/12

Ethics committee reference number

IR.TBZMED.REC.1400.636

Health conditions studied

1

Description of health condition studied

In the present study, no diseases will be examined and products will be administered by healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma Drug Concentration

Timepoint

0.5-24 hours in predetermined time intervals after drug administration

Method of measurement

HPLC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group will receive one test drug capsule. Blood samples will be taken from the volunteers for 24 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Drugs

2

Description

Control group: Control group will receive one reference drug product. Blood samples will be taken from the volunteers for 24 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category

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

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

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Email

pzakeri@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Sameie

Street address

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

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Samiei.moh@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Fatak Shimi Pars Co.

Proportion provided by this source

100

Public or private sector

Public

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Contact

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Email

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

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

Data Dictionary

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