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 Committe, 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

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

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

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.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
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

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

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
pzakeri@tbzmed.ac.ir

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
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
pzakeri@tbzmed.ac.ir

Person responsible for updating data

pzakeri@tbzmed.ac.ir

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

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

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