Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Fasted state in vivo bioequivalence study for Imatinib 100 mg capsule manufactured by Avicenna Co. in comparison to German brand AQVIDA

Protocol summary

Study aim
Investigating bioequivalence of Imatinib 100 mg capsule with innovator product manufactured in Germany

Design
The present study is a randomized, single-blind, single-dose, 2-sequence, 2-period crossover trial. Twenty-four healthy volunteer will enter the study based on random numbers table as two groups of twelve people.

Settings and conduct
This study will be conducted on 24 healthy volunteers in Faculty of Pharmacy, Tabriz University of Medical Sciences. A table of random numbers will be used to assign the volunteers into two groups of study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: General Health including Liver, Heart and Kidney health; being at the age of 20-60 years old. Non-inclusion criteria: Smoking; history of cardiovascular disease; history of liver and kidney disease; pregnancy; alcohol and drug addiction; history of drug allergy

Intervention groups
Intervention group: In this group, a single dose of 100 mg imatinib capsule made by Avicenna company is taken orally and then after a washout period of one week, a 100 mg imatinib capsule made by AQVIDA Co. Germany is administered. Control group: In this group, a single dose of 100 mg imatinib capsule made by AQVIDA Co. Germany y is taken orally and then after a washout period of one week, a 100 mg imatinib capsule made by Avicenna company is administered.

Main outcome variables
Bio equivalence between two products based on FDA guidelines

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210519051345N6**
Registration date: **2021-11-14, 1400/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-14, 1400/08/23**
Update count: **0**

Registration date
2021-11-14, 1400/08/23

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
2021-11-06, 1400/08/15

Expected recruitment end date
2021-12-06, 1400/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Fasted state in vivo bioequivalence study for Imatinib 100 mg capsule manufactured by Avicenna Co. in comparison to German brand AQVIDA

Public title
In vivo bioequivalence study of Imatinib 100 mg capsule

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General Health including Liver, Heart and Kidney health Being at the age of 25-55 years old
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 **60 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
A table of random numbers will be used. Random number tables are generated by computers that randomly set the numbers. First, a two-digit code (according to the number of volunteers, which is 24) is given to each candidate, and after creating the table, a random selection of numbers is made. To select sample people from the table, randomly start from a point in the table moving in the direction of the row or column. The selection of the point can be done by closing the eyes and placing a finger or the tip of a pen on the table. Moving in the direction of the row or column does not make any difference and this is optional. After this, the path numbers are controlled, which will be dealt with two types of numbers, one of which is smaller than the volume of the population of the study and the other is larger than the number of the population. Only smaller numbers should be considered and selected. The selected number is actually the individual code that is selected as the sample. This should be continued until enough small number can be selected based on the number of volunteers.
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
3rd Floor; No.2 Central Building; Tabriz University of Medical Sciences; Daneshgah street
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Approval date
2021-10-04, 1400/07/12
Ethics committee reference number
IR.TBZMED.REC.1400.638

Health conditions studied

1

Description of health condition studied
Fasted state in vivo bioequivalence study
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug Plasma Concentration
Timepoint
Blood samples will be obtained prior to dosing (baseline) and 0.5; 1.0; 1.5; 2.0; 2.5; 3.0; 3.5, 4.0; 4.5, 6.0; 8.0; 12.0; 24.0; 48.0 and 72.0 h post-dose.
Method of measurement
High performance liquid chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, a single dose of 100 mg imatinib capsule made by Avicenna company is taken orally and then after a washout period of one week, a 100 mg imatinib capsule made by AQVIDA Co. Germany is administered.

Category
Treatment - Drugs

2

Description
Control group: In this group, a single dose of 100 mg imatinib capsule made by AQVIDA Co. Germany y is taken orally and then after a washout period of one week, a 100 mg imatinib capsule made by Avicenna company is administered.
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; Attar Neishaboori street; Golgasht street
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 Samiei
Street address
3rd Floor; No.2 Central Building; Tabriz University of Medical Sciences; Daneshgah street
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
Avicenna 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
Street address
Tabriz University of Medical Sciences; Faculty of Pharmacy; Attar Neishaboori street; Golgasht street
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
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Phone
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Email
pzakeri@tbzmed.ac.ir

Person responsible for updating data

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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51664-14766
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Email
pzakeri@tbzmed.ac.ir

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
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