Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Bioequivalence study of Ibrutinib 140 mg capsule (Lifoza) manufactured by Dr. Abidi company versus Imbruvica 140 mg in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of Ibrutinib 140mg capsule manufactured by Dr. Abidi company (Lifoza) versus originator brand (Imbruvica) manufactured by Janssen company

Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct

The study is a single-blinded, cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (24h). The interval between these two periods, the washout period, is one week. In the first round of the study, the candidates divide into two groups. the first group receives a test capsule and the second group receives a brand capsule. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. In the second period, the first group will consume the brand capsule, and the second group will consume the test capsule. These steps are performed in Radin Laboratory in Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: General Health (Liver, Heart, and Kidney), Body Mass Index (18-28), Informed consent, Age (18-55 years old) Exclusion criteria: Smoking, History of cardiovascular disease, History of liver and kidney disease, Alcohol and drug addiction, History of allergy to Ibrutinib

Intervention groups

Intervention group 1: Imbruvica 140mg capsule as a reference Intervention group 2: Lifoza 140mg as a test Volunteers are divided into 2 groups. The first group consumes test medicine and the second group consumes brand one. In the second period which is run after one week, the first group will consume the brand and the second group will consume the test medicine.

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration, Half-life of drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N78**
Registration date: **2023-07-04, 1402/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-04, 1402/04/13**
Update count: **0**

Registration date

2023-07-04, 1402/04/13

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-23, 1402/04/02

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Ibrutinib 140 mg capsule (Lifoza) manufactured by Dr. Abidi company versus Imbruvica 140 mg in healthy volunteers in the fasted condition

Public title

Bioequivalence study of Ibrutinib 140 mg

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)

Exclusion criteria:

Smoking History of cardiovascular disease History of liver and kidney disease Alcohol and drug addiction History of allergy to Ibrutinib

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **28**

Blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: Dr. Abidi's medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug. In the second period that is run after one week, the First group will consume brand medicine and the second group will consume test one.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blinded clinical trial (volunteers). Dr. Abidi's Ibrutinib and Originator brand capsules are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-05-22, 1402/03/01

Ethics committee reference number

IR.TBZMED.REC.1402.168

Health conditions studied

1

Description of health condition studied

This study is performed on healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24h after drug administration

Method of measurement

Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description

Time to reach maximum plasma concentration

Timepoint

After intervention

Method of measurement

Time to reach the maximum drug concentration in plasma is recorded.

2

Description

Extent of absorption

Timepoint

After intervention

Method of measurement

Calculation of area under curve of concentration -time

Intervention groups

1

Description

Intervention group: single dose, one oral capsule 140mg(Imbruviva) manufactured by Janssen, as a reference product

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, one oral Lifoza 140 mg capsule manufactured by Dr. Abidi company as a test product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radin Laboratory

Full name of responsible person

Javad Shokri

Street address

No.22, first floor, Moalem st., Abureihan St

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5154995671

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shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Amir Razavian

Street address

Tehran, 8 km of Shahid Lashkari Highway Abidi Boulevard No. 72

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Province

Tehran

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7636313897

Phone

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Fax

+98 21 4450 4787

Email

info@abidi-diabetes.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

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

Javad Shokri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
These data are as secure between researchers and related industries.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available