

# 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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5154995671

**Phone**

+98 914 313 5843

**Fax**

**Email**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

7636313897

**Phone**

+98 21 4452 2451

**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

**Street address**

No 4, 10th Ave. Boostan Street, Roshdieh, Tabriz

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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