

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### In vivo fasted-state bioequivalence study of Baricitinib tablets manufactured by Sobhan oncology Pharmaceutical Co. compared to innovator product

#### Protocol summary

##### Study aim

In vivo fasted-state bioequivalence study of Baricitinib 4 mg capsule

##### Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. 24 healthy male volunteers will participate randomly in the study as two twelve-person groups. Each volunteer will receive a single dose in two periods. In one period the test and in another period the reference formulation. Therefore, each volunteer will be his own "Control". To randomly assign participants in two groups, the lottery method will be used.

##### Settings and conduct

After oral administration of one 4 mg tablet to volunteer, the blood samples will be collected in predetermined time intervals up to 48 hours. The plasma samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. The concentration of drug will be measured by HPLC with mass spectroscopy detector. The study will be performed without blinding in Faculty of Pharmacy, Tabriz University of Medical Sciences .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney diseases), Age (18-59 years old) Exclusion criteria: Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy

##### Intervention groups

Intervention group will receive a single oral dose of test drug product (Baricitinib 4 mg tablet manufactured by Sobhan Oncology) and Control group will receive a single dose of reference drug product (Baricitinib 4 mg capsule manufactured by Lilly). Blood samples will be taken from the volunteers for 48 hours at the mentioned time points after drug administration and the plasma will be stored in freezer until analysis. In both groups, breakfast and

lunch will be served two and six hours after drug administration, respectively.

##### Main outcome variables

Drug plasma concentration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220211053992N24**

Registration date: **2024-01-24, 1402/11/04**

Registration timing: **prospective**

Last update: **2024-01-24, 1402/11/04**

Update count: **0**

##### Registration date

2024-01-24, 1402/11/04

##### Registrant information

##### Name

Hadi Valizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 8801

##### Email address

valizadehh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-06, 1402/11/17

##### Expected recruitment end date

2024-10-21, 1403/07/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
In vivo fasted-state bioequivalence study of Baricitinib tablets manufactured by Sobhan oncology Pharmaceutical Co. compared to innovator product

**Public title**  
In vivo Bioequivalence study of Baricitinib tablets

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
General Health (in terms of Liver, Heart and Kidney diseases) Age between 18 to 59 years  
**Exclusion criteria:**  
Smoking History of cardiovascular, liver, and kidney disease Pregnancy Alcohol and drug addiction History of drug allergy

**Age**  
From **18 years** old to **59 years** old

**Gender**  
Male

**Phase**  
Bioequivalence

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **24**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**

## Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

## Street address

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

## City

Tabriz

## Province

East Azarbaijan

## Postal code

51664-14766

## Approval date

2024-01-14, 1402/10/24

## Ethics committee reference number

IR.TBZMED.REC.1402.795

## Health conditions studied

1

### Description of health condition studied

In the present study, the products will be administered to healthy volunteers.

### ICD-10 code

### ICD-10 code description

## Primary outcomes

1

### Description

Plasma concentration of drug

### Timepoint

0.5-48 hours in predetermined time intervals after drug administration

### Method of measurement

HPLC (High performance liquid chromatography)

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Intervention group: Intervention group will receive a single oral dose of test product (Baricitinib 4 mg capsule manufactured by Sobhan Oncology Co., Iran) in fasted state. Blood samples will be collected for 48 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

### Category

Treatment - Drugs

## 2

### Description

Control group: Control group will receive a single oral dose of reference product (Baricitinib 4 mg tablet manufactured by Lilly) in fasted state. Blood samples will be collected for 48 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively

### 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

Hadi Valizadeh

##### Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori St., Golgash St.t

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

51664-14766

##### Phone

+98 41 3334 8801

##### Fax

+98 41 3334 4798

##### Email

valizadehh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Parviz Shahabi

##### Street address

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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

51664-14766

##### Phone

+98 41 3334 8801

##### Fax

+98 41 3334 4798

### Email

shahabip@tbzmed.ac.ir

### Grant name

### Grant code / Reference number

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

No

### Title of funding source

Sobhan Oncology 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

Hadi Valizadeh

#### Position

Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

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

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51664-14766

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Hadi Valizadeh

#### Position

Professor

#### Latest degree

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#### Other areas of specialty/work

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

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**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**

Not applicable

**Data Dictionary**

Not applicable