

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### A cross over bioequivalence study of Nilotinib 150mg capsule of Sobhan Oncology compared to Tasigna 150 mg capsule manufactured by Novartis in 24 healthy volunteers under fasting condition

#### Protocol summary

##### Study aim

Comparison of the bioavailability of Nilotinib capsules after a single dose of 150 mg, manufactured by Sobhan Oncology and Novartis .

##### Design

The study is a cross-over double-blind study. 24 healthy volunteers using the random option in excel software will be assigned a code, and depending on the code, the first half will receive the test, and the second half will receive reference drugs. In each phase of the study, 14 blood samples will be received from the individual.

##### Settings and conduct

On the day of sampling, after 10 hours of fasting, the volunteers come to Kharazmi Plasma Center in Islamshahr ( No. 13, 1st Shehamat Alley, Ali Ibn Abitalib St., Namaz Square,) and receive one capsule of the test or reference drug with 240 ml of water and blood samples are taken at 0.5,1,1.5,2,2.5, 3, 3.5,4,6,8,10,24,32,48 hours after drug administration, after plasma separation, the samples were transferred to a -70 freezer and finally the concentration of drug in plasma will be determined according to the LCMSMS method.After a one-week wash out period, the process of drug administration is done vice versa.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy adult male (18 - 55 yrs) and sterile or post menopausal female subjects, Body weight must be  $\geq 50$  kg and  $< 100$  kg, with a body mass index (BMI)  $> 18$  but  $< 33$ . Laboratory parameter values must fall within the normal range Exclusion criteria:

Contraindication to receiving nilotinib. Smokers or user of tobacco products , A past medical history of clinically significant Electrocardiogram abnormalities, or a history/family history of long QT-interval syndrome.

##### Intervention groups

Comparing the blood concentration of nilotinib from Sobhan Oncology company with Novartis company sample

#### Main outcome variables

Plasma concentration caused by test and reference drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220209053979N4**

Registration date: **2022-08-09, 1401/05/18**

Registration timing: **prospective**

Last update: **2022-08-09, 1401/05/18**

Update count: **0**

##### Registration date

2022-08-09, 1401/05/18

##### Registrant information

##### Name

Roya Talari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8880 0892

##### Email address

talari\_r@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-06, 1401/06/15

##### Expected recruitment end date

2022-09-12, 1401/06/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
A cross over bioequivalence study of Nilotinib 150mg capsule of Sobhan Oncology compared to Tasigna 150 mg capsule manufactured by Novartis in 24 healthy volunteers under fasting condition

**Public title**  
A bioequivalence study of Nilotinib 150mg capsule of Sobhan Oncology compared to Tasigna 150 mg capsule manufactured by Novartis in 24 healthy volunteers under fasting condition

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Healthy adult male (18 - 55 yrs) and sterile or post menopausal female subjects Body mass index (BMI) >18 but <30. Laboratory parameter values must fall within the normal range  
**Exclusion criteria:**  
Smokers History of clinically significant Electrocardiogram abnormalities, or a history/family history of long QT-interval syndrome.

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

**Gender**  
Both

**Phase**  
Bioequivalence

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: **24**  
More than 1 sample in each individual  
Number of samples in each individual: **14**  
6 ml blood samples

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

**Randomization description**  
volunteers number 1-12 will be assigned code A and volunteers number 13-24 will be allocated code B. On the first phase, the first 12 candidates will be prescribed the test drug and the second 12 volunteers will receive the reference drug, and in the second phase, it is vise versa, that the first 12 volunteers who were given the test drug in the first phase will receive the reference drug and second group of volunteers who have received the reference drug in the first phase, will take the test drug. But non of the prescriber, volunteer, and the person analyzing the drug, know the difference between code A and B, and they do not know which medicine is prescribing.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The drug (test or reference drug) is removed from the

original packaging the day before the study and packaged in small disposable containers. Therefore, it is not in the original packaging and also the visual appearance and size of the test and reference capsules are the same , none of the volunteer nor the prescriber know which drug is being administered. The relevant code is also written on the sample collecting tubes of each volunteer, neither the analyzer knows the test or reference drug sample is analyzing.

**Placebo**  
Not used

**Assignment**  
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Research Ethics Committee of the Institute of Pharmaceutical Science

**Street address**

16 th Azar, Tehran University of medical science

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۷۳۳۱۴۱

#### Approval date

2022-07-17, 1401/04/26

#### Ethics committee reference number

IR.TUMS.TIPS.REC.1401.028

## Health conditions studied

### 1

#### Description of health condition studied

Investigation of bioequivalence of Nilotinib 150 mg capsule manufactured by Sobhan Oncology company in comparison to the Tagigna150 mg capsule manufactured by Novartis company

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Plasma concentration of Nilotinib of Sobhan Oncology and Tasigna manufactured by Novartis Company

#### Timepoint

0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 32, 48 h

#### Method of measurement

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Oral administration of a 150 mg capsule manufactured by Sobhan Oncology Company to 12 healthy volunteers in fasting condition with 240 ml of water. Then 14 blood samples are taken from volunteers at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 32, 48 hours after drug administration. In the second phase after a wash out period of one week, this group takes Novartis medicine and blood samples are taken at the same times

#### Category

Other

### 2

#### Description

Intervention group: Oral administration of a 150 mg capsule of Tasigna manufactured by Novartis Switzerland to 12 healthy volunteers in fasting condition with 240 ml of water. Then 14 blood samples are taken from each volunteer at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 32, 48 hours. In the second phase after one week washout period they receive Sobhan Oncology drug and again at the same time they give a blood sample.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kharazmi Plasma Center of Islamshahr

##### Full name of responsible person

Sara Solgi

##### Street address

No. 13. First Shahamat Alley, Ali Ibn Abitaleb Street, Namaz Square, Islamshahr,

##### City

Islamshahr

##### Province

Tehran

##### Postal code

3313679886

##### Phone

+98 21 5669 4726

##### Fax

+98 21 5637 8236

##### Email

Info@kpcir.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sobhan Oncology

##### Full name of responsible person

Payan Pourhashemi

##### Street address

No. 5, Aviz Alley, Alvand St, Argantin Sq.

##### City

Tehran

##### Province

Tehran

##### Postal code

4337188657

##### Phone

+98 21 8387 9000

##### Email

info@sobhanoncology.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sobhan Oncology

#### 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

Kharazmi Plasma Center

##### Full name of responsible person

Roya Talari

##### Position

executor of Study

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

No.13, First Shahamat Alley, Ali Ibn Abitaleb Street, Islamshahr

##### City

Islamshahr

##### Province

Tehran

##### Postal code

3313679886

**Phone**  
+98 21 5669 4726  
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talari\_r@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kharazmi Plasma Center  
**Full name of responsible person**  
Roya Talari  
**Position**  
executor of study  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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3313679886  
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**Email**  
talari\_r@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kharazmi Plasma Center  
**Full name of responsible person**

Roya Talari  
**Position**  
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**Latest degree**  
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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

The study is confidential and must be allowed by Sobhan Oncology for publication

### 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