Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A cross over bioequivalence study of Niloitinib 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 Soban Ancology 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 vise 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 ≥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 Soban 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 Niloitinib 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 Niloitinib 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 Sobbhan 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

liquid chromatography mass spectrometry (LCMSMS)

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 take 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 volunteers at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 32, 48 hours. In the seconde 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
Email
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
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
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
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
Email
talari_r@yahoo.com

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