Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A cross over bioequivalence study of sunitinib 50 mg capsule of Sobhanoncology compared to Sutent 50 mg capsule manufactured by Pfizer in 24 healthy volunteers under fasting condition

Protocol summary

Study aim
Evaluation of bioequivalence of Sobhan Oncology Company's Sanitinib Capsules in comparison with the sample of Sutent brand made by Pfizer Company

Design
The study is cross-over. 24 healthy volunteers randomly receive one of the two test or reference drugs in each phase of the study, a total of 13 blood samples is received from the individual

Settings and conduct
On the sampling day, after 10 hours fasting, the volunteers will take a single dose of 20 mg test or reference drug with 240 ml of water, and blood saomples are taken at times of 1، 2، 3، 4، 5، 6، 7، 8، 9، 10، 11، 12، 24، 36، 48 and 72 hours after drug administration, then samples are transferred to -70 freezer after plasma separation finally the plasma drug concentration is determined according to liquid chromatography mass spectrometry (LCMSMS) method. After a wash out period of week in the second phase, the candidates who received the test drug in the first phase will receive the reference sample, and the people who had previously received the reference sample will receive the test sample in the second phase.

Participants/Inclusion and exclusion criteria
Completely healthy volunteer in clinical trials, with normal heart rate and blood pressure; people who have not participated in another clinical trial in the last 3 months.

Intervention groups
One capsule of Sunitinib 50 mg of Sobhan Oncology Company along with 240 ml of water is prescribed to 12 volunteers. The second group: 12 volunteers are prescribed one capsule of Pfizer Sutent along with 240 ml of water. 3 weeks later, this study will be repeated and the group that previously received the test drug now receives the Pfizer drug and vice versa.

Main outcome variables
Plasma concentration of test and reference drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220209053979N3**
Registration date: **2022-08-08, 1401/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-08, 1401/05/17**
Update count: **0**

Registration date
2022-08-08, 1401/05/17

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
2022-07-21, 1401/04/30

Expected recruitment end date
2022-08-12, 1401/05/21

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A cross over bioequivalence study of sunitinib 50 mg capsule of Sobhanoncology compared to Sutent 50 mg capsule manufactured by Pfizer in 24 healthy volunteers under fasting condition

Public title

A bioequivalence study of Sunitinib 50 mg capsules of Sobhanoncology compared to Sutent 50 mg Capsule manufactured by Pfizer in 24 healthy volunteers under fasting condition

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

No signs of acute or chronic disease during the screening. Non-smokers No known history of drugs abuse at least 6 months prior to being included in the test Volunteer's consent to use two medically effective methods of contraception, at least one of which is a barrier method (from the date of screening to the completion of the study and within 10 weeks after the last dose of drugs) The subject's voluntary willingness to sign written informed consent.

Exclusion criteria:

Burdened allergic history Use of any over-the-counter or prescription drugs (including vitamins, minerals, herbal drugs, in particular containing tutsan), use of any dietary supplements less than 14 days before the day of taking the study drug, and throughout the study Participation in any clinical studies less than 90 days prior to the beginning of the current clinical study. Any blood/plasma donation and/or bleeding in the amount of 450 ml, as well as if the volunteers were transfused with whole blood or its components less than 60 days before the start of the study. Subjects with abnormal heart rhythm (HR at rest ≥ 100 bpm or ≤ 50 bpm) and BP (systolic BP ≤100 mmHg or diastolic BP ≤60 mmHg or systolic BP ≥140 mm Hg or diastolic BP ≥ 90 mmHg) on the day of the examination or in the history.

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: **17**

About 6 cc of blood per sample

Randomization (investigator's opinion)

Not randomized

Randomization description

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 packed in small disposable containers. Therefore, because it is not in the original packaging, the volunteer and the prescriber do not know which drug is being administered to volunteer. Each volunteeris also assigned a code that, depending on the code, half of them receive the test drug in the first phase and the other half receive the reference drug, and then in the second phase, vice versa, the group that took the test drug in the first phase in the second phase will receive reference drug. And the group that received the reference medicine takes the test medicine.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences

Street address

16 Azar St., Enghelab Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-07-13, 1401/04/22

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.020

Health conditions studied

1

Description of health condition studied

Bioequivalence study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of Sunitinib 50 mg of Sobhan

Oncology and Sutent manufactured by Pfizer Company

Timepoint

0, 1, 2, 3, 4, 5, 6, , 8, 9, 10, 11, 12, 24, 36, 48 , 72 hours after drug administration

Method of measurement

liquid chromatography mass spectrometry (LCMSMS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral administration of a 50 mg sunitinib capsule made by Sobhan Oncology Company to 12 healthy volunteers in fasting state with 240 ml of water. Then 16 blood samples are taken from the volunteers at 0, 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 24, 36, 48 and 72 hours after drug administration. In the second phase after a wash out period of 3 weeks this group take Pfizer's drug in and give a blood sample at the above times

Category

Treatment - Drugs

2

Description

Intervention group: Oral administration of a 50 mg sunitinib capsule made by Pfizer Company to 12 healthy volunteers in fasting state with 240 ml of water. Then 16 blood samples are taken from the volunteers at 0, 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 24, 36, 48 and 72 hours after drug administration. In the second phase after a wash out period of 3 weeks this group take Sunitinib of Sobhan Oncology in and give a blood sample at the above times

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 Ave., Alvand street, Arjantin Sq.,

City

Tehran

Province

Tehran

Postal code

4337188657

Phone

+98 21 8879 9924

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, Namaz Sq.,

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
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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
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Province
Tehran
Postal code
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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