Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of Sunitinib 50 mg capsule manufactured by Zistdaru Danesh (Sunixha) versus Sutent 50 mg in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of Sunitinib 50 mg capsules manufactured by Zistdaru Danesh company (Sunixha) versus the originator brand (Sutent) manufactured by Pfizer company

Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization.

Settings and conduct

The study has two series of healthy volunteers and is single-blinded, cross-over, and fasting. The study will take two 72-hour periods to complete. There are two weeks between these two times. The study's candidates are divided into two groups for the initial phase. A test capsule is given to the first group, while a brand capsule is given to the second. Volunteers take blood samples both before and after administering the medication. Following drug extraction, samples are prepared for examination. The first group will take the brand capsule during the second period, while the second group will take the trial capsule. These actions are carried out in Tabriz's Radin Laboratory.

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 Sunitinib

Intervention groups

Intervention group 1: Sutent 50 mg capsule as a reference Intervention group 2: Sunixha 50mg as a test Volunteers are divided into two groups. The first group consumes test medicine, and the second group consumes brand medicine. In the second period, which is run after two weeks, 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: **IRCT20200105046010N75**
Registration date: **2023-05-02, 1402/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-02, 1402/02/12**
Update count: **0**

Registration date

2023-05-02, 1402/02/12

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

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence study of Sunitinib 50 mg capsule manufactured by Zistdaru Danesh (Sunixha) versus Sutent 50 mg in healthy volunteers in the fasted condition

Public title
Bioequivalence study of Sunitinib 50mg capsule
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 Sunitinib
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: **40**
Blood sample
Randomization (investigator's opinion)
Randomized
Randomization description
People in the mentioned age group are invited to participate through the advertisement. After that, people who are in good health are selected. Each candidate receives a number between 1 and 24. A plastic ball with the numbers inscribed on it is poured into a container, then stirred. Next, balls are randomly pulled out of the container. Zistdaru Danesh's medicine is considered to be the first 12 numbers, and the recipient of the original brand is considered to be the second 12 numbers. The subjects are unaware of taking either the brand or test medication. The first group will take brand-name medication during the second session, which is conducted a week later, while the second group will take a test medication.
Blinding (investigator's opinion)
Single blinded
Blinding description
A single-blinded clinical trial (volunteers) was used in this study. The executor removes the test Sunitinib and Originator brand capsules from their packaging and places them in coordinated cans. Volunteers won't be made aware of the brand or experimental dose 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 committe
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
2023-03-06, 1401/12/15
Ethics committee reference number
IR.TBZMED.REC.1402.019

Health conditions studied

1

Description of health condition studied
.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration
Timepoint
0, 1, 2, 3, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 9,10,11, 12, 24, 48, 72h 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 50mg(Sutent) manufactured by Pfizer, as a reference product
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, one oral Sunixha 50 mg capsule manufactured by Zistdaru Danesh 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, Azadi alley, Moalem st., Abureihan St
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Tabriz
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5154995671
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shokri.j@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
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street,
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5165665931
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+98 41 3334 1249
Email
research-vice @tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zistdaru Danesh 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
Javad Shokri
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact

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Javad Shokri

Position

Professor

Latest degree

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Person responsible for updating data

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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