

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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 committee

**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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5154995671

##### Phone

+98 914 313 5843

##### Fax

##### Email

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,

##### City

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##### Province

East Azarbaijan

##### Postal code

5165665931

##### Phone

+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

##### Street address

No 4, 10th Ave. Boostan Street, Roshdieh, Tabriz

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## Person responsible for scientific inquiries

### Contact

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Professor  
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**Other areas of specialty/work**  
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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