

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Bioequivalence study of Nilotinib 200mg capsule manufactured by Zistdaru Danesh versus Tasigna 200 mg in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of Nilotinib 200mg capsule manufactured by Zistdaru Danesh company (Nitagxha) versus originator brand (Tasigna) manufactured by Novartis company

Design

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

Settings and conduct

The study is a single-blinded, cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (72h). The interval between these two periods is one week. In the first round of the study, the candidates divide into two groups. the first group receives a test capsule and the second group receives a brand capsule. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. These steps are performed in Radin Laboratory in Tabriz.

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 Nilotinib

Intervention groups

Intervention group 1: Tasigna 200mg capsule as a reference Intervention group 2: Nitagxha 200mg as a test

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: **IRCT20200623047902N21**

Registration date: **2022-12-23, 1401/10/02**

Registration timing: **prospective**

Last update: **2022-12-23, 1401/10/02**

Update count: **0**

Registration date

2022-12-23, 1401/10/02

Registrant information

Name

Elham Ghasemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6696 5196

Email address

ghasemian@zistdaru.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Nilotinib 200mg capsule manufactured by Zistdaru Danesh versus Tasigna 200 mg in healthy volunteers in the fasted condition

Public title

Bioequivalence study of Nilotinib 200mg 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 Nilotinib

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: **16**

Blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: Zistdaru Danesh's medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blinded clinical trial (volunteers). Zistdaru Danesh's Nilotinib and Originator brand capsules are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Tabriz University of Medical Sciences

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

2022-12-19, 1401/09/28

Ethics committee reference number

IR.TBZMED.REC.1401.848

Health conditions studied

1

Description of health condition studied

This study is performed on healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

Immediately before drug consumption and , 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24, 48 and 72 h 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 200mg(Tasigna) manufactured by Novartis, as a reference product

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, one oral Nitagxha 200 mg capsule manufactured by Zistdaru Danesh company as 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

Email

shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zistdaru danesh Co.

Full name of responsible person

Hooshmand Ilka

Street address

No. 404, 4th floor, Rose mall complex, Kharazi highway

City

Tehran

Province

Tehran

Postal code

1498711347

Phone

+98 21 4231 8100

Email

ilka@Zistdaru.ir

Grant name

Grant code / Reference number

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

Yes

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

Zistdaru danesh Co.

Full name of responsible person

Elham Ghasemian

Position

Deputy director of research and development

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Zistdaru danesh Co., second floor, No.98, Bozorgmehr St., Vesale Shirazi St., Enghelab St

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1417833714

Phone

+98 21 6696 5196

Email

ghasemian@zistdaru.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zistdaru danesh Co.

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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