Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of erlotinib150mg tablet, manufactured by Zistdaru Danesh co. (Erloxha) Versus Tarceva 150 in healthy volunteers

Protocol summary

Study aim
Bioequivalence Study of Ėrlotinib tablet 150 mg manufactured by Zistdaru Danesh company versus originator brand (Tarceva 150) manufactured by Roche company

Design
Bioequivalence study, crossover, single blind, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct
The study will be conducted in a single-blinded, cross-over and fasting, and on two series of healthy volunteers. The study will be conducted in two periods (72h). The interval between these two periods, which is called the wash-out time, is determined 2 weeks. In the first round of the study, the candidates are divided into two groups and the first group receives a test tablet and the second group receives a brand tablet. Blood samples are taken by the doctor immediately before and after the drug is taken by the volunteers, and the steps for preparing the samples include plasma separation and drug extraction to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: General Health (Liver, Heart, and Kidney), Body Mass Index (18-28), Informed consent, Age (18-60 years old) Exclusion criteria: Smoking, History of cardiovascular disease, History of liver and kidney disease, Alcoholism and Narcoticism, History of allergy to Ėrlotinib

Intervention groups
In this study, two groups of intervention and control are not applicable. Both groups will receive test-reference medicine and testing on two different occasions, and therefore the test results will be independent of individual differences and will only indicate differences in the formulation of the two drugs.

Main outcome variables
Maximum drug concentration, Time to reach maximum drug concentration, Half-life of drug

General information

Reason for update
Changing the sampling center

Acronym

IRCT registration information
IRCT registration number: **IRCT20200623047902N6**
Registration date: **2021-08-14, 1400/05/23**
Registration timing: **prospective**

Last update: **2024-07-20, 1403/04/30**
Update count: **1**

Registration date
2021-08-14, 1400/05/23

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
2021-09-06, 1400/06/15

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence study of erlotinib150mg tablet, manufactured by Zistdaru Danesh co. (Erloxha) Versus Tarceva 150 in healthy volunteers

Public title
Bioequivalence study of erlotinib 150 mg

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-60 years old)

Exclusion criteria:
Smoking History of cardiovascular disease History of liver and kidney disease Alcoholism and Narcoticism History of allergy to erlotinib

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

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 and 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: Erloxha 150) and the second 12 no.s are considered as (second sequence: Tarceva 150 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). Erloxha and Tarceva tablets 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 Committee of the Research Institute of Pharmaceutical Sciences, Tehran University of

Street address
Zistdaru Danesh Co., Second floor, No.98, Bozorgmehr St., Velsale Shirazi st., Enghelab St.

City
Tehran

Province
Tehran

Postal code
1417833714

Approval date
2021-07-10, 1400/04/19

Ethics committee reference number
IR.TUMS.TIPS.REC.1400.069

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. The subject of the study is the bioequivalence study of Erlotinib tablet 150 mg of test and reference in healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration

Timepoint
Before, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24, 36,48 and 72h after drug consumption

Method of measurement
HPLC -MASS-MASS

Secondary outcomes

1

Description
Pharmacokinetic parameters

Timepoint
After intervention

Method of measurement
Theoretical and pahrmacokinetic equations

Intervention groups

1

Description

Intervention group: single dose, one oral tablet of Tarceva 150 mg (Erlotinib) manufactured by Roche, as reference product

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, one oral tablet of Erloxha 150 mg (Erlotinib) manufactured by Zistdaru Danesh as test product

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shokri laboratory

Full name of responsible person

Javad Shokri

Street address

No.48,Ferdos Street

City

Tabriz

Province

East Azarbaijan

Postal code

5167874434

Phone

+98 41 3384 2724

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zistdaru Danesh Company

Full name of responsible person

Hooshmand Ilka

Street address

No. 10, 8th floor, Faraz building, Sahand St., Beheshti St.

City

Tehran

Province

Tehran

Postal code

1559836438

Phone

+98 21 4231 8000

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 Company

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 company

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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zistdaru Danesh company

Full name of responsible person

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Position

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Person responsible for updating data

Contact
Name of organization / entity
Zistdaru Danesh company
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
City
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1417833714
Phone
+98 21 6696 5196
Email
Ghasemian@zistdaru.ir

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 researcher 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