Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

in- Vivo Bioequivalence study of Erlotinib tablet 150 mg Abidi Pharma (LOTIVA® 150 mg) with brand drug (TARCEVA® 150 mg, Rosche, Switzerland) in Iranian healthy volunteers.

Protocol summary

Study aim
In- Vivo Bioequivalence study of Erlotinib tablet 150 mg Abidi Pharma. with brand drug (TARCEVA® 150 mg, Rosche, Switzerland) in Iranian healthy volunteers.

Design
In-vivo bioequivalence study of Erlotinib tablet 150 mg Abidi Pharma. in compared with reference drug (TARCEVA® 150 mg, Rosche, Switzerland). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

Settings and conduct
This study is carried out in Simin Baspar Tayf-Gostar Company, Tabriz, Iran. The study population is 24 healthy Iranian volunteers.This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 72 hours with a two-week wash-out period.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18-55 years, body mass index (BMI) in the range of 18-28. Exclusion criteria: History of heart, kidney and liver disease, Pregnancy, Drug addiction, Smoking

Intervention groups
Single dose Erlotinib tablet 150 mg Abidi Pharma. Control group: brand drugs (TARCEVA® 150 mg, Rosche, Switzerland)

Main outcome variables
Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N51**
Registration date: **2021-12-27, 1400/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-27, 1400/10/06**
Update count: **0**

Registration date
2021-12-27, 1400/10/06

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
2021-12-25, 1400/10/04

Expected recruitment end date
2022-06-25, 1401/04/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
in- Vivo Bioequivalence study of Erlotinib tablet 150 mg Abidi Pharma (LOTIVA® 150 mg) with brand drug

(TARCEVA® 150 mg, Rosche, Switzerland) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence Test of Erlotinib tablets with brand drug (TARCEVA® 150 mg, Rosche, Switzerland)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health Body mass index between18-28 Informed consent Being at the age of 18-55 years old
Exclusion criteria:
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug
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**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.
Blinding (investigator's opinion)
Single blinded
Blinding description
Candidates are not aware of receiving the test drug or brand one. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and Brand drugs 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 drug.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-11-15, 1400/08/24
Ethics committee reference number
IR.TBZMED.REC.1400.743

Health conditions studied

1

Description of health condition studied
Bio equivalence test
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma drug concentration
Timepoint
Sampling times in this study will be 0, 0:30, 1, 1:30, 2, 2:30, 3, 3:30, 4, 4:30, 5, 6, 8, 10, 24, 48, 72 hours after prescribing the tablet.
Method of measurement
High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One test tablet (Erlotinib tablet 150 mg produced by Abidi Pharma.) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector
Category
Treatment - Other

2

Description
Control group: One Reference tablet (TARCEVA® 150

mg, Rosche, Switzerland) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of Erlotinib in plasma samples will be measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

Street address

No.48, Ferdos square

City

Tabriz

Province

East Azarbaijan

Postal code

5167874434

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+98 41 3384 2724

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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abidi Pharmaceutical Company

Full name of responsible person

Amir Razavian

Street address

No. 72, Abidi Boulevard, 8 km of Shahid Lashkari Highway, Tehran

City

Tehran

Province

East Azarbaijan

Postal code

7636313897

Phone

+98 21 4452 2451

Email

info@abidi-diabetes.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Abidi Pharmaceutical 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

Persons

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

Name of organization / entity

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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 updating data

Contact

Name of organization / entity
Simin Baspar Teyf Gostar Company

Full name of responsible person
Dariush Omidar

Position
Lab. Manager

Latest degree
Master

Other areas of specialty/work
Others

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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
All information and data of the study will remain secured based on the agreement established between researcher and drug producer.

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
Yes - There is a plan to make this available

Title and more details about the data/document
Only protocol and methods of study are sharable

When the data will become available and for how long
The access to data will be possible after finishing of project (almost 6 months after receiving of IRCT Code).

To whom data/document is available
Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used
Projects information's for any publications is not allowed.

From where data/document is obtainable
By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document
These information are confidential and be under disposal of the project's contractor. Upon request, the information will be accessed to the applicant by the Executor's email after receiving contractor's consent.

Comments