Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Erlotinib 150 mg tablets produced by Kimia pharmaceutical Co versus Tarceva® (Roche company) in 30 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Kimia pharmaceutical Co Erlotinib 150 mg tablets versus Tarceva (Roche Co.)

Design

Single dose, randomized and crossover bioequivalence study of Erlotinib 150 mg tablets (Kimia Co.) with Tarceva (Roche Co.) in 30 healthy male in two groups under fasting condition.Data will be analyzed with Exel and SPSS software.

Settings and conduct

Study place: Medication Applied Research Center affiliated to Tabriz University of Medical Science. Blood and plasma sample analysis will be performed in Imam Reza Medical Research and Trainning hospital. Eighteen healthy male volunteers will receive each of two, test or reference Erlotinib 150 mg tablets, in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 14 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before receiving the drug and 72 hours after that at determined time points: 0.5، 1، 1.5، 2، 2.5، 3، 4، 5، 6، 8، 12، 24، 48 and 72 hours.

Participants/Inclusion and exclusion criteria

Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma, DM, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group (Test): Erlotinib 150 mg tablets by Kimia Co. is the test product. In each period, 15 of 30 subjects will be given single oral dose of this product. Control group (Reference): Tarceva (Roche Co.) is the reference product. In each period, 15 of 30 subjects will be given single dose of this product.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N7**
Registration date: **2021-03-26, 1400/01/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-26, 1400/01/06**
Update count: **0**

Registration date

2021-03-26, 1400/01/06

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-14, 1399/12/24

Expected recruitment end date

2021-06-14, 1400/03/24

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

Scientific title
Randomized, single-dose, crossover comparative bioequivalence study of the Erlotinib 150 mg tablets produced by Kimia pharmaceutical Co versus Tarceva® (Roche company) in 30 healthy males under fasting conditions

Public title
Study of absorption and elimination rate of Erlotinib 150 mg tablets in comparison with standard tablet of Erlotinib (Tarceva).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The weight limit for each volunteer between 60-100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Erlotinib or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg Taking any medicine during two week before dosing.
Age
From **18 years** old to **60 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **15**
Candidates of the sequences must take one of the Iranian or brand drugs, if the first sequence of the volunteers received the Iranian drug after the washout period, they must receive the brand drug. In fact,every single volunteers is used as control for himself.
Randomization (investigator's opinion)
Randomized
Randomization description
First, a table of random numbers from 1 to 30 is created. The table numbers are assigned to individuals in the order in which the candidates enter the list on the day of the experiment, and the candidates in two groups with numbers 1-15 and numbers 16-30 will receive reference and test medicine, respectively.
Blinding (investigator's opinion)
Not blinded
Blinding description
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 Science
Street address
Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-03-01, 1399/12/11
Ethics committee reference number
IR.TBZMED.REC.1399.1117

Health conditions studied

1

Description of health condition studied
Lung and pancreatic cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax), AUC (Area Under the Concentration-Time Curve)
Timepoint
At 0 (before intervention), 0.5، 1،1.5، 2، 2.5، 3، 5، 4، 6، 8، 12، 24، 48، 72 hour after dosing
Method of measurement
High-performance liquid chromatography—mass spectrometry (HPLC-MS) and using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSSIntervention groups

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (Test): Erlotinib 150 mg tablets, produced by Kimia pharmaceutical Co. is the test product. In each period, 15 of 30 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group (Reference): Erlotinib 150 mg tablets (produced by Roche co.) is the reference product. In each period, 15 of 30 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center
Full name of responsible person
Dr Hamed Hamishehkar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kimia pharmaceutical Co
Full name of responsible person
Esmaeil Moazeni
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No. 1462, Bu Ali Biotechnology Park, Opposite North Campus, University of Tehran, North Kargar St., Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kimia pharmaceutical 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
Dr Hamed Hamishehkar
Position
Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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