Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Gefitinib 250 mg tablets produced by Kimia pharmaceutical Co versus Iressa® (AstraZeneca company) in 30 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Kimia pharmaceutical Co Gefitinib 250 mg tablets versus Iressa® (AstraZeneca co.).

Design

Single dose, randomized and crossover bioequivalence study of Gefitinib 250 mg tablets (Kimia Co.) with Iressa® in 30 healthy male in two groups under fasting condition.Data will be analyzed with Excel and SPSS software.

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for Blood and plasma sample analysis: Imam Reza Medical Research and Trainning Hospital. 30 healthy male volunteers received each of two test or reference Gefitinib 250 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 120 hours after that at determined time points: 0, 0.5، 1، 2، 3، 4، 5، 6، 8، 12، 24 ،48 ،72 ،96 and 120 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): Gefitinib 250 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): Iressa® (AstraZeneca 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: **IRCT20200407046981N6**
Registration date: **2021-03-24, 1400/01/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-24, 1400/01/04**
Update count: **0**

Registration date

2021-03-24, 1400/01/04

Registrant information

Name
Fatima Molavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3336 2700

Email address
molavif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2021-08-06, 1400/05/15

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 Gefitinib 250 mg tablets produced by Kimia pharmaceutical Co versus Iressa® (AstraZeneca company) in 30 healthy males under fasting conditions

Public title

Study of absorption and elimination rate of Gefitinib 250 mg tablets in comparison with standard tablet of Iressa® (AstraZeneca company).

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

The weight limit for each volunteer is between 60 and 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 that will be assessed.

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 Regular smoker who smokes more than ten cigarettes daily. 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

Individuals will be recruited with advertising. 30 volunteers will be allocated to two sequences randomly by lottery method.The number was allocated according to their entrance to volunteers' list in screening day.

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.1399.1147

Health conditions studied

1

Description of health condition studied

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، 2، 3، 4، 5، 6، 8، 12، 24 ،48 ،72 ،96 and 120 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): Gefitinib 250 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): Gefitinib 250 mg tablets (produced by AstraZeneca 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
Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5165665811
Phone
+98 41 3336 7914
Fax
+98 41 3336 7914
Email
hamishehkar.hamed@gmail.com
Web page address
https://darc.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kimia pharmaceutical Co
Full name of responsible person
Esmaeil Moazeni
Street address
No. 1462, Bu Ali Biotechnology Park, Opposite North Campus, University of Tehran, North Kargar St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1111111111
Phone
+98 21 8801 2946
Fax
+98 21 8822 0700
Email
mitra.movahedian@gmail.com
Web page address
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
Hamed Hamishehkar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmaceutics
Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5165665811
Phone
+98 41 3336 7914
Email
Hamishehkar.hamed@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Jaber Emami

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

Street address
Hezarjarib St., School of Pharmacy and Pharmaceutical Sciences , Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 7111

Fax
+98 31 3668 0011

Email
Emami@pharm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Fatima Molavi

Position
PhD student of Pharmaceutics

Latest degree
Medical doctor

Other areas of specialty/work
Pharmaceutics

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3336 2700

Fax

Email
Molavif@tbzmed.ac.ir

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