Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Imatinib 100 mg capsules produced by Kimia pharmaceutical Co versus Gleveec® (NOVARTIS company) in 18 healthy males under fasting conditions

Protocol summary

Study aim
To demonstrate bioequivalence of single dose test formulation of Kimia pharmaceutical Co Imatinib 100 mg capsules versus Gleevec (Novartis Co.)

Design
Single dose, randomized and crossover bioequivalence study of Imatinib 100 mg capsules (Kimia pharmaceutical Co.) with Gleevec capsules (Novartis co.) in 18 healthy male under fasting condition.

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. Eighteen healthy male volunteers received each of two test or reference Imatinib capsule in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 14 days, if the first sequence, received Iranian medicine, they will receive brand medicine. Blood samples will taken from all participants before receiving the drug and 72 hours after that at determined time points: 2, 2.5, 3, 4, 6, 8, 12, 24, 48 and 72 hours.

Participants/Inclusion and exclusion criteria
Inclusion 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 group1 (Test): Imatinib 100 mg capsules by Kimia pharmaceutical Co. is the test product. In each period, 9 of 18 subjects will be given single oral dose of this product. Control group2 (Reference): Gleevec 100 mg capsules (Novartis co.) is the reference product. In each period, 9 of 18 subjects will be given single oral 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: **IRCT20200407046981N4**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date
2020-12-02, 1399/09/12

Registrant information

Name
Fatima Molavi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-02-19, 1399/12/01

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 Imatinib 100 mg capsules produced by Kimia pharmaceutical Co versus Gleveec® (NOVARTIS company) in 18 healthy males under fasting conditions

Public title

Study of absorption and elimination rate of Imatinib 100 mg capsules in comparison with standard tablet of Imatinib (Imatinib).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The weight limit for each volunteer is between 60 and 100 kg. Only non-smokers are allowed to participate. They must be healthy in terms of liver and kidney status, respiratory system, and other general health characteristics that will be assessed.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Imatinib or any ingredients. 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 (during past 5 years), DM, psychosis or glaucoma. 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: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly selected with advertising. 18 volunteers categorized in two sequences randomly and the type of drug (Sample and Brand drug) will prescribe with lottery. Thus, if the first sequence of volunteers received Iranian medicine, they will receive brand medicine after the washout period.

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

2020-08-02, 1399/05/12

Ethics committee reference number

IR.TBZMED.REC.1399.496

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 the Imatinib capsules of test and reference in healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

At 0 (before dosing), 1, 2, 2.5, 3, 4, 6, 8, 12, 24, 48 & 72 hour after dosing

Method of measurement

high-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

During 2 months after intervention

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSSIntervention groups

Intervention groups

1

Description

Intervention group (Test): Imatinib 100 mg capsule, produced by Kimia pharmaceutical Co. is the test product. In each period, 9 of 18 subjects will be given single oral dose of this product.

Category

Treatment - Drugs

2

Description

Intervention group (Reference): Gleevec 100 mg capsules (produced by Novartis co.) is the reference product. In each period, 9 of 18 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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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

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Person responsible for scientific inquiries

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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
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