

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Imatinib 400 mg capsules produced by Kimia pharmaceutical Co versus Gleevec® (NOVARTIS company) in 30 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Kimia pharmaceutical Co Imatinib 400 mg capsules versus Gleevec (Novartis Co.)

Design

Single dose, randomized and crossover bioequivalence study of Imatinib 400 mg capsules (Kimia Co.) with Gleevec® 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 Training Hospital. 30 healthy male volunteers received each of two test or reference Imatinib 400 mg capsules 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 at determined time points 0, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 24, 48, 72 and 96 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 $\leq$ 90/60 mm/Hg or BP $\geq$ 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 400 mg capsules by Kimia pharmaceutical Co. is the test product. In each period, 15 of 30 subjects will be given single oral dose of this product. Control group2 (Reference): Gleevec 400

mg capsules (Novartis co.) is the reference product. In each period, 15 of 30 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: **IRCT20200407046981N9**

Registration date: **2021-05-01, 1400/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-01, 1400/02/11**

Update count: **0**

Registration date

2021-05-01, 1400/02/11

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-25, 1400/02/05
Expected recruitment end date
 2021-07-27, 1400/05/05
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 400 mg capsules produced by Kimia pharmaceutical Co versus Gleveec® (NOVARTIS company) in 30 healthy males under fasting conditions

Public title
 Study of absorption and elimination rate of Imatinib 400 mg capsules in comparison with standard tablet of Imatinib (Gleveec).

Purpose
 Health service research

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, kidney, respiratory system, mental and other general health characteristics that will be assessed.
Exclusion criteria:
 Known hypersensitivity or idiosyncratic reaction to Imatinib or any ingredients. Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 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

2021-03-15, 1399/12/25

Ethics committee reference number

IR.TBZMED.REC.1399.1175

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), AUC (Area Under the Concentration-Time Curve)

Timepoint

At 0 (before dosing), 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 24, 48, 72 and 96 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 SPSS Intervention groups

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (Test): Imatinib 400 mg capsule, 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): Gleevec 400 mg capsules (produced by Novartis 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

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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Position

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Latest degree

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Other areas of specialty/work

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Full name of responsible person

Fatima Molavi

Position

PhD student of Pharmaceutics

Latest degree

Medical doctor

Other areas of specialty/work

Pharmaceutics

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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

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