

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Population Pharmacokinetics study of Imatinib in CML patients

Protocol summary

Summary

Inter individual variations of pharmacokinetics of Imatinib Mesylate as first line treatment of CML cause different therapeutic responses and side effects. Therapeutic drug monitoring of imatinib make it possible to adjust dosage regime and assess the adherence of patients to the treatment. In this study individual covariates and genetic factor which may affect pharmacokinetics of Imatinib in CML patients will evaluated and modeling will done according to important and effective factors. One trough and one random plasma concentration will extracted and according to demographic parameters the model will be make.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050612206N1**

Registration date: **2014-05-15, 1393/02/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-15, 1393/02/25

Registrant information

Name

Ehsan Mohajeri

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 1320 5253

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Population Pharmacokinetics study of Imatinib in CML patients

Public title

Population Pharmacokinetics study of Imatinib

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with CML in chronic phase who take Imatinib from diagnosis and have no other disease.

Exclusion Criteria: taking Interfron or Hydroxyurea in past or during the study; taking drugs that induce or inhibit liver microsomal enzymes and patients in accelerated or blastic phases.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **220**

Randomization (investigator's opinion)

N/A

Randomization description
Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kerman University of Medical Sciences

Street address

Somaye cross road

City

Kerman

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

065/93/5

Health conditions studied**1****Description of health condition studied**

Chronic myeloid leukaemia (CML)

ICD-10 code

C92.1

ICD-10 code description

Chronic myeloid leukaemia [CML], BCR/ABL-positive

Primary outcomes**1****Description**

Trough plasma concentration

Timepoint

Before taking the dose

Method of measurement

HPLC

Secondary outcomes**1****Description**

Hematological response

Timepoint

every 3 months

Method of measurement

CBC Check

Intervention groups**1****Description**

Observational Study

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Bahonar Hospital

Full name of responsible person

Ehsan Mohajeri

Street address

Garani Street, Shahid Bahonar Hospital

City

Kerman

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Somaye cross road

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Kerman

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact**

Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty