Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)
Phone
+98 34 1320 5253
Email address
881334001@collegian.kmu.ac.ir

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/ک

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
City
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
Kerman University of Medical Sciences
Full name of responsible person
Ehsan Mohjeri
Position
Assistant Professor
Other areas of specialty/work
Street address
Shahid Bahonar Hospital
City
Kerman
Postal code
Phone
+98 913 199 7114
Fax
Email
ehsandaru@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical sciences
Full name of responsible person
Ehsan Mohajeri
Position
Assistant Professor
Other areas of specialty/work
Street address
Shahid Bahonar Hospital
City
Kerman
Postal code
Phone
+98 34 1226 3787
Fax
Email
ehsandaru@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Ehsan Mohajeri
Position
Assistant Professor
Other areas of specialty/work
Street address
Garani Street, Shahid Bahonar Hospital
City
Kerman
Postal code
Phone
+98 34 1226 3787
Fax
Email
Web page address

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