Clinical Trial Protocol
Iranian Registry of Clinical Trials
07 Jul 2019

Efficacy of Imatinib Mesylate in the treatment of refractory cutaneous chronic Graft Versus-Host Disease

Protocol summary

Summary
A total of 30 patients admitted to Bone Marrow Transplant Clinic of Dr. Shariati Hospital who underwent allogen bone marrow transplantation due to leukemia, thalassemia, multiple myeloma, and aplastic anemia, and have clinical signs of chronic coetaneous Graft Versus-Host Disease (CGVHD) whose symptoms are not improved by using corticosteroids and cyclosporine will be under treatment with Imatinib Mesylate for six months; 100 mg Imatinib Mesylate daily for the first month, 200 mg daily for the second and third months, and 400 mg daily for the next three months is prescribed. Before treatment and after six months, the extent of coetaneous involvement will be calculated in percentage. The intensity of the involvement will be determined through biopsy in pathology as well. Patients are included in the study with consent and in full awareness.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201302261030N12
Registration date: 2013-06-03, 1392/03/13
Registration timing: retrospective

Recruitment status
Recruitment complete
Funding source
Hematology-Oncology and SCT Research Center

Expected recruitment start date
2012-08-28, 1391/06/07
Expected recruitment end date
2012-11-20, 1391/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of Imatinib Mesylate in the treatment of refractory cutaneous chronic Graft Versus-Host Disease

Public title
Effect of Imatinib Mesylate in patients undergone allogeneic bone marrow transplantation who show chronic coetaneous involvement Graft Versus-Host Disease.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria 1- The patient shall undergo allogen bone marrow transplantation and have clinical and pathological cutaneous CGVHD criteria. 2- Patient’s cutaneous signs are not improved by taking corticosteroids with doses of 0.5 mg/kg at least for 3 months and cyclosporine. 3- The cutaneous signs shall be active. 4- The patient shall be aged between 16 to 60 years old. Exclusion Criteria 1- Pregnancy 2- Having a history of taking Rituximab.

Age
From 16 years old to 60 years old

Gender
Both

Phase
2

Groups that have been masked
None

Sample size

Last update: 0
Update count: 0
Registration date: 2013-06-03, 1392/03/13

Registrant information

Name
Mahdi Jalili

Name of organization / entity
Hematology-Oncology & SCT Research Center

Country
Iran (Islamic Republic of)

Phone
+98 21 8490 2662

Email address
m_jalili@farabi.tums.ac.ir
Target sample size: 28

Randomization (investigator's opinion)
- N/A

Randomization description
N/A

Blinding (investigator's opinion)
- Not blinded

Blinding description
- Not used

Placebo
- Not used

Assignment
- Single

Other design features

Secondary ids
- empty

Ethics committees

1

Ethics committee
- Name of ethics committee
  Hematology-Oncology and SCT Research Center
  Ethics Committee

- Street address
  Kargar Ave. Shariati Hospital

- City
  Tehran

- Country
  Iran (Islamic Republic of)

- Approval date
  2012-07-22, 1391/05/01

- Ethics committee reference number
  1391/5/1

Health conditions studied

1

Description of health condition studied
- cutaneous cGVHD

ICD-10 code
- T86.0

ICD-10 code description
- Graft-versus-host reaction or disease

Primary outcomes

1

Description
- The extent of cutaneous involvement

Timepoint
- At the start of treatment and in the end of 6 month

Method of measurement
- Skin examination

Secondary outcomes

1

Description
- Extent of skin involvement in pathology

Timepoint
- At the start of treatment and in the end of 6 month

Method of measurement
- Severity of involvement in pathology

2

Description
- Side effect frequency

Timepoint
- Every month after treatment up to 6 months

Method of measurement
- Examination and following treatment

Intervention groups

1

Description
- Imatinib: 100 mg Imatinib Mesylate daily for the first month, 200 mg daily for the second and third months, and 400 mg daily for the next three months

Category
- Treatment - Drugs

Recruitment centers

1

Recruitment center
- Name of recruitment center
  Hematology-Oncology and SCT Research Center

- Full name of responsible person
  Zohreh Shahabi

- Street address
  Kargar Ave Shariati Hospital

- City
  Tehran

- Country
  Iran (Islamic Republic of)

Sponsors / Funding sources

1

Sponsor
- Name of organization / entity
  Hematology-Oncology and SCT Research Center

- Full name of responsible person
  Zohreh Shahabi

- Street address
  Kargar Ave Shariati Hospital

- City
  Tehran

- Country
  Iran (Islamic Republic of)

Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hematology-Oncology and SCT Research Center

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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Hematology-Oncology and SCT Research Center
Full name of responsible person
Marjan Mehri
Position
MD
Other areas of specialty/work
Kargar Ave, Shariati Hospital
City
Tehran
Country
Iran (Islamic Republic of)
Postal code
+98 21 8490 2635
Phone
horcbmt@tums.ac.ir
Fax
Email
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hematology-Oncology and SCT Research Center
Full name of responsible person
Marjan Mehri
Position
MD
Other areas of specialty/work
Kargar Ave, Shariati Hospital
City
Tehran
Country
Iran (Islamic Republic of)
Postal code
+98 21 8490 2635
Phone
horcbmt@tums.ac.ir
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