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

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

Registrant information
Name
Mahdi Jalili

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

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Iran (Islamic Republic of)

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+98 21 8490 2662

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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
Target sample size: 28

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
- Hematology-Oncology and SCT Research Center Ethics Committee

Street address
- Kargar Ave. Shariati Hospital

City
- Tehran

Country
- Iran (Islamic Republic of)

Postal code

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 involvment

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 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
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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