Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

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:
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
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Iran (Islamic Republic of)
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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
No information

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

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 fallowing 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

Street address

City
Tehran

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
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
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
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Person responsible for updating data

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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