Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2662

Email address

m_jalili@farabi.tums.ac.ir

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

MD

Other areas of specialty/work

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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