Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy of Azithromycin in prophylaxis of acute GVHD following allo-SCT in Hematology- oncology research center of shariati Hospital

Protocol summary

Summary

For prevention of acute GVHD after allogeneic hematopoietic cell transplantation 100 patients with hematological malignancies who underwent Allo stem cell transplantation were randomly assigned to group A and B to receive azithromycin or placebo. Patients and the transplantation team were blinded for the assigned arm. Age 16-60 and malignant disease is inclusion criteria and age below16 and non malignant disease is exclusion criteria. Patients of 2 groups receive drug or placebo 500mg daily beginning at the start of the conditioning regimen (day 6 pre-transplantation) and continuing through day 12 post-transplantation. All subjects received their usual immunosuppressive regimen within the study period. Clinical assessment of acute GVHD and oral mucositis were done with scoring system in weekly periods from day 0-100 post-transplant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403281030N16**
Registration date: **2014-04-05, 1393/01/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-05, 1393/01/16

Registrant information

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Hematology-Oncology & SCT Research Center
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Recruitment status

Recruitment complete

Funding source

Hematology, Oncology and SCT Research Center

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Azithromycin in prophylaxis of acute GVHD following allo-SCT in Hematology- oncology research center of shariati Hospital

Public title

Evaluation efficacy of Azithromycin in prophylaxis of bone marrow transplant complication

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 16-60 years old; malignant hematologic disease; allogeneic stem cell transplantation and first stem cell transplantation.
Exclusion criteria: age below 16 years old; non malignant disease; second stem cell transplantation.

Age

From **16 years** old to **60 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hematology, Oncology and SCT Research Center
Street address
Kargar Ave Shariati Hospital
City
Tehran
Postal code
Approval date
2013-08-18, 1392/05/27
Ethics committee reference number
27/05/92

Health conditions studied

1

Description of health condition studied
Acute myeloblastic leukaemia
ICD-10 code
C92.0
ICD-10 code description
Acute myeloblastic leukaemia

2

Description of health condition studied
Acute lymphoblastic leukaemia
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukaemia

3

Description of health condition studied
Chronic myeloid leukaemia
ICD-10 code
C92.1
ICD-10 code description
Chronic myeloid leukaemia

4

Description of health condition studied
Multiple myeloma
ICD-10 code
C90.0
ICD-10 code description
Multiple myeloma

Primary outcomes

1

Description
Acute GVHD
Timepoint
Every week till 100 day after transplantation
Method of measurement
Clinical assessment

Secondary outcomes

1

Description
Oral mucositis
Timepoint
Every week till 100 day after transplantation
Method of measurement
Clinical assessment

Intervention groups

1

Description
Azithromycine 500g orally from day -6 to +12 of transplantation
Category
Treatment - Drugs

2

Description
Placebo 500g orally from day -6 to +12 of transplantation
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Hematology, Oncology and SCT Research Center
Full name of responsible person
Ardeshir Ghavamzadeh
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hematology, Oncology and SCT Research Center
Full name of responsible person
Kamran Alimoghadam
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Kargar Ave. Shariati Hospital
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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

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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