Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of N-Acetylcystein on prevention of Acute Renal injury due to Cyclosporine Administration in patients undergoing bone marrow transplantation

Protocol summary

Summary
The goal of this randomized and double blind clinical trial is assessment of anti nephrotoxicity effect due to cyclosporine of N-Acetylcystein in patients with Acute Leukemia whom undergo allogeneic full matched bone marrow transplantation. Patients randomized in two group. One group treated with N-Acetylcystein after transplantation and others give placebo. Renal functions will follow with lab test for renal injury.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201306031030N14**
Registration date: **2013-06-06, 1392/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2013-06-06, 1392/03/16

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
2012-07-22, 1391/05/01
Expected recruitment end date
2013-07-23, 1392/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of N-Acetylcystein on prevention of Acute Renal injury due to Cyclosporine Administration in patients undergoing bone marrow transplantation

Public title
The effect of N-Acetylcystein on prevention of Acute Renal injury due to Cyclosporine Administration in patients undergoing bone marrow transplantation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1- Patients with acute myeloid leukemia or acute lymphocytic leukemia 2- Full match Allogeneic Bone Marrow Transplantation 3- Age between 15-60 year old 4- Treatment of Cyclosporin after transplantation Exclusion criteria: 1- Patient under 15 year old 2- Patient with diabetes, chronic kidney disease, liver disorder or hypertension
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
2-3

Groups that have been masked
No information
Sample size
Target sample size: **60**
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 Ethics Committee
Street address
Shariati Hospital, Kargar Ave
City
Tehran
Postal code
Approval date
2012-07-01, 1391/04/11
Ethics committee reference number
1391/4/11

Health conditions studied

1

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

2

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

3

Description of health condition studied
Acute Renal injury
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum Creatinin
Timepoint
6 and 3 days before transplantation and 3, 9 and 5 day after transplantation
Method of measurement
Lab test

Secondary outcomes

1

Description
Urine NGAL
Timepoint
6 and 3 days before transplantation and 3, 9 and 5 day after transplantation
Method of measurement
Lab test

Intervention groups

1

Description
N-acetyl cysteine IV 100mg/kg daily. Drug start on the morning before starting chemotherapy and will continue until day 15 after transplantation.
Category
Treatment - Drugs

2

Description
Placebo Start on the morning before starting chemotherapy and will continue until day 15 after transplantation.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology-Oncology and SCT Research Center
Full name of responsible person
Sara Ataei
Street address
Shariati Hospital, Kargar Ave
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
Shariati Hospital, Kargar Ave
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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
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Person responsible for scientific inquiries

Contact
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Hematology Oncology and SCT Research Center
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Molok Hajibabaei
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Postal code
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+98 21 8490 2662
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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