

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

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

2012-07-22, 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

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

Sara Ataei

Position

ParmD

Other areas of specialty/work**Street address**

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horcbmt@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hematology Oncology and SCT Research Center

Full name of responsible person

Molok Hajibabaei

Position

Clinical pharmacy /Associated prof

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact**Name of organization / entity**

Hematology-Oncology & SCT Research Center

Full name of responsible person

Mahdi Jalili

Position

MD

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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