Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of N-acetyl cysteine in preventing the incidence and severity of mucositis in patients undergoing bone marrow transplantation

Protocol summary

Summary

Our purpose in this double blinded randomized study is to evaluate the N-acetyl cysteine effect on mucositis prevention in patient with acute myeloid leukemia (AML) & acute lymphoblastic leukemia (ALL) & Myelodysplastic syndrome (MDS) whose received Busulfan and/or Cyclophosphamide before Hematopoietic stem cell transplantation (HSCT) in Shariati Teaching Hospital, Tehran, Iran. Sixty-four patients will be randomized in two groups with balanced block randomization method. One group will receive N-acetyl cysteine IV(100mg/kg) and another group will receive placebo per day. Therapy will start on the morning before starting chemotherapy and will continue until day +15. Response assessment will include: Mucositis, glutathione peroxidase levels in the serum and infectious complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303301030N13**
Registration date: **2013-04-10, 1392/01/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-10, 1392/01/21

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

2012-11-05, 1391/08/15

Expected recruitment end date

2013-06-05, 1392/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of N-acetyl cysteine in preventing the incidence and severity of mucositis in patients undergoing bone marrow transplantation

Public title

The effect of N-acetyl cysteine in preventing mucositis in patients undergoing bone marrow transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Patients receiving chemotherapy regimens (Endoxane- busulfan) in bone marrow transplantation. 2- The patient over the 18 years old of age. 3-Informed consent forms signed by the patients. Exclusion: 1- Participating in other clinical trial (drug or supplement) 2- Dissatisfaction of patient.

Age

From **18 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **64**
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
91/4/11

Health conditions studied

1

Description of health condition studied
Mucositis (oral)
ICD-10 code
K12.3
ICD-10 code description
Oral mucositis (ulcerative)

2

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

3

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

4

Description of health condition studied
MDS
ICD-10 code
D46
ICD-10 code description
Myelodysplastic syndromes

Primary outcomes

1

Description
Oral mucositis
Timepoint
Daily at the first day of chemotherapy until the patients discharged
Method of measurement
Clinical observation

Secondary outcomes

1

Description
Glutathione peroxidase serum level
Timepoint
At the first day of admission and 14 days after the transplantation
Method of measurement
Lab Test (ng/dl)

2

Description
Fever incidence
Timepoint
Daily until discharg
Method of measurement
Measurement of oral temperature

3

Description
Duration of neutropenia
Timepoint
Daily until discharg
Method of measurement
Lab Test

4

Description

Consumption of TPN
Timepoint
During Hospitalization
Method of measurement
Medical Records

5

Description
Antibiotic consumption
Timepoint
During Hospitalization
Method of measurement
Medical Records

Intervention groups

1

Description
N-acetyl cysteine IV 00mg/kg daily
Category
Treatment - Drugs

2

Description
Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology-Oncology and SCT Research Center
Full name of responsible person
Amirhossein Moslehi
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
Amirhossein Moslehi
Position
ParmD
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Hematology Oncology and SCT Research Center
Full name of responsible person
Molok Hajibabaei
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Clinical pharmacy /associated prof
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Person responsible for updating data

Contact

Name of organization / entity
Hematology-Oncology and SCT Research Center

Full name of responsible person
Mahdi Jalili

Position
MD

Other areas of specialty/work

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Fax

Email

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