Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of prophilacticN-Acetylcysteine (NAC) in Poor Graft Function (PGF) and Prolonged Thrombocytopenia (PT) in haploidentical Haematopoietic stem cells transplantation (HSCT) patients: A phase 3, triple-blinded, randomized, placebo-controlled trial

Protocol summary

Study aim
evaluation of prophilactic NAC in Poor Graft Function and Prolonged Thrombocytopenia after haploidentical HSCT
Design
A Triple-blinded, Randomized, Placebo-controlled phase 3 Trial on 20 patients
Settings and conduct
Patients who have inclusion criteria that have admitted in HSCT wards of Shariati hospital will received oral NAC treatment (400 mg 3 times per day) or placebo from 7 days pre-HSCT to 30 days post-HSCT (-7 to +30)
Participants/Inclusion and exclusion criteria
patients aged 18 to 55 years who were diagnosed with acute leukemia with complete remission and scheduled to receive haplo-HSCT
Intervention groups
Patients who have inclusion criteria after complete informed consent will received oral NAC treatment (400 mg 3 times per day) or placebo from 7 days pre-HSCT to 30 days post-HSCT (-7 to +30)
Main outcome variables
Cumulative incidence of poor graft function (PGF) and prolonged isolated thrombocytopenia (PT) after 2 mounts post HSCT; Cumulative incidence acute GvHD after 100 daye post HSCT; Cumulative incidence Relaps after 1 year post HSCT; Cumulative incidence TRM after 1 year post HSCT; One year relaps free survival (RFS) ; One year overal survival (OS)

General information

Reason for update
change of control group from historical control group to double blind placebo control
Acronym
IRCT registration information

IRCT registration number: **IRCT20140818018842N19**
Registration date: **2020-08-16, 1399/05/26**
Registration timing: **retrospective**

Last update: **2020-11-01, 1399/08/11**
Update count: **2**
Registration date
2020-08-16, 1399/05/26

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-10, 1399/05/20
Expected recruitment end date
2020-08-10, 1399/05/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluation of prophilacticN-Acetylcysteine (NAC) in Poor Graft Function (PGF) and Prolonged Thrombocytopenia (PT) in haploidentical Haematopoietic stem cells transplantation (HSCT) patients: A phase 3, triple-blinded, randomized, placebo-controlled trial

Public title
NAC for prevention of PGF and PT in Haploidentical HSCT
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients aged 18 to 55 years diagnosed with acute leukemia complete remission scheduled to receive haplo-HSCT
Exclusion criteria:
Bronchial asthma NAC allergy Intolerance to oral drug
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a randomized controlled clinical trial with parallel design. We apply balanced block randomization method for randomization. Randomization sequence will be give to a person out of the research team in order to perform concealment.
Blinding (investigator's opinion)
Triple blinded
Blinding description
NAC and placebo are made in the form of similar tablets by the pharmaceutical company. Only one person on the study team who is responsible for randomization takes the tables, puts them in similar packages and encodes as a sequence of numbers according to a list of Balanced Block Randomization. Upon arrival of the each eligible patient, the coded package will be provided with a label that includes the drug numerical code, patient name, and study code. Except for the above person, no body, including the treating physician, the person in charge of data collection and analysis, statistical analyzer, and the patient himself, are aware of the type of drug. Allocation concealment samples are done by the people of the center that they and patients do not have any information about the researcher's aim.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hematology , Oncology and Stem Cell Transplantation Research Center- Tehran University of Medical Sc
Street address
Shariati Hospital, Kargar shomali Ave., Tehran
City
Tehran
Province
Tehran
Postal code
1411713135
Approval date
2020-01-08, 1398/10/18
Ethics committee reference number
IR.TUMS.HORCSCT.REC.1398.001

Health conditions studied

1

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

2

Description of health condition studied
Acute lymphoblastic leukemia
ICD-10 code
C91.02
ICD-10 code description
Acute lymphoblastic leukemia, in relapse

Primary outcomes

1

Description
prolonged isolated thrombocytopenia (PT)
Timepoint
60 days after HSCT
Method of measurement
Complete Blood Count (CBC), Bone Marrow Biopsy (BMB), Bone Marrow Aspiration (BMA)

2

Description

Poor Graft Function

Timepoint

60 days after HSCT

Method of measurement

Complete Blood Count (CBC), Bone Marrow Biopsy (BMB), Bone Marrow Aspiration (BMA)

Secondary outcomes

1

Description

Cumulative incidence acute GvHD

Timepoint

After 100 daye post HSCT

Method of measurement

Physical exam and lab test

2

Description

Cumulative incidence Relaps

Timepoint

After 1 year post HSCT

Method of measurement

Bone Marrow aspiration and biopsy

3

Description

Cumulative incidence TRM

Timepoint

After 100 daye post HSCT

Method of measurement

Follow up visit to check relaps or death

4

Description

One year relapse free survival (RFS)

Timepoint

After 100 days post HSCT

Method of measurement

Bone Marrow aspiration and biopsy, Physical exam and lab test

5

Description

One year overal survival (OS)

Timepoint

after 100 day post HSCT

Method of measurement

Follow up visit

Intervention groups

1

Description

Intervention group: patients scheduled to receive haplo-HSCT consecutively screened for inclusion in the study and will received oral NAC (tablet 200mg), 400 mg 3 times per day(total dose 1200 mg) from 7 days pre-HSCT to 30 days post-HSCT (-7 to +30)

Category

Treatment - Drugs

2

Description

Control group: patients scheduled to receive haplo-HSCT consecutively screened for inclusion in the study and will received placebo 3 times per day from 7 days pre-HSCT to 30 days post-HSCT (-7 to +30)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran University of Medical Sci

Full name of responsible person

Maryam Barkhordar

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Shariati hospital, Kargar shomali Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Barkhordar
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
IPD collected for the primary outcome measure only
When the data will become available and for how long
immediate after publication
To whom data/document is available
no body
Under which criteria data/document could be used
after research committee confirmation
From where data/document is obtainable
Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran University of Medical Sciences,

ctu@tums.ac.ir

not provided

What processes are involved for a request to access data/document

Comments