

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of N Acetyl cysteine on platelet engraftment post autologous bone marrow transplantation in comparison to control group

Protocol summary

Study aim

The evaluation of efficacy of prophylactic use of N-Acetyl-cysteine on accelerating platelet engraftment in multiple myeloma and lymphoma patients post Auto-HSCT in comparison to placebo group

Design

Clinical trial with control group, with parallel group, triple blinded, phase 3 with 30 patients, for randomization
Random Allocation software is used.

Settings and conduct

After randomization volunteers who accept to participate in the study, and are admitted in transplant ward at Omid Hospital in Isfahan, Iran, in addition to routine care and treatment based on triple blinded fashion (patients, investigators, health care providers, analyzer are blinded) receive N acetyl cysteine (intervention group) or placebo(control group). During admission platelet will be checked daily and after that weekly at-least for 3 weeks, after gathering data, the statistics will analyze qualitative data by Wallis-kruskal and quantitative data with unilateral variance. A p-value less than 0.05 (typically ≤ 0.05) is statistically significant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with multiple myeloma or lymphoma who are eligible for Auto-HSCT
Exclusion criteria: history of allergic reaction to N-Acetyl cysteine or its ingredients, or Bronchial Asthma

Intervention groups

Intervention group in addition to routine treatment receive N-Acetyl cysteine oral 400 mg q 8 hour one week before and two weeks after auto-HSCT. like intervention group, control group receive routine treatment in addition to placebo in the same schedule.

Main outcome variables

The days which platelet infusion are not required.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211123053165N1**

Registration date: **2021-12-22, 1400/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-22, 1400/10/01**

Update count: **0**

Registration date

2021-12-22, 1400/10/01

Registrant information

Name

Rasoul Ghasemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3226 1922

Email address

rasoolqasemian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N Acetyl cysteine on platelet engraftment post autologous bone marrow transplantation in comparison to control group

Public title

Effect of N-Acetyl-cysteine On platelet Engraftment post Auto-HSCT

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Multiple Myeloma who are eligible for Auto-HSCT
Patients with Lymphoma who are eligible for Auto-HSCT

Exclusion criteria:

History Of Allergic Reaction to N-Acetyl cysteine or its ingredients
History of Bronchial Asthma

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

After calculating sample size, because there are intervention and control groups, these data is inserted in online Random Allocation software. The software randomly give two sequences of number, which distributed in two groups. According to entrance of every patient, assigns a number to each volunteer. Then regard to the number is belonged to which group, patients will be in control or intervention group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The company that produced drug and placebo, packed them in different color boxes and with them send us a closed letter in which explain each color is related to drug or placebo. We will open this letter at the end of study, when the data analyzed. So participants, investigators, health care providers, information gathering responsible and Analyzer have been blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Science

Street address

No 20, Farhangian A, Irajmirza Alley, Kahran Alley, North Golzar

City

Esfahan

Province

Isfahan

Postal code

8154916877

Approval date

2021-11-12, 1400/08/21

Ethics committee reference number

IR.MUI.MED.REC.1400.627

Health conditions studied**1****Description of health condition studied**

MULTIPLE MYELOMA

ICD-10 code

C90.0

ICD-10 code description

Multiple myeloma

2**Description of health condition studied**

LYMPHOMA

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

3**Description of health condition studied**

Auto-Hsct

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Median Platelet number post auto-Hsct

Timepoint

During admission daily then weekly for at least 3 weeks

Method of measurement

complete blood count test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with Multiple Myeloma or Lymphoma that their diseases are in complete remission and are candidate of Auto-HSCT, will be received N-Acetyl cysteine tablets, in form of 200mg tablets which produced by Toliddarou pharmaceutical company, 400 mg every 8 hours(21 days).

Category

Treatment - Drugs

2

Description

Control group: patients with Multiple Myeloma or Lymphoma that their diseases are in complete remission and are candidate of Auto-HSCT, will be received Placebo tablets, in the same form as control group, which produced by Toliddarou pharmaceutical company, two tablets every 8 hours(21 days).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Rasoul Ghasemian

Street address

Motahari

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8174673461

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Email

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Web page address

<https://omid.mui.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

No 4, Ishan Medical University, Hezarjirib Street

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esfahan

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siavash@med.mui.ac.ir

Web page address

<https://research.mui.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

20

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

Esfahan University of Medical Sciences

Full name of responsible person

Rasoul Ghasemian

Position

Hematology-Oncology Fellowship

Latest degree

Specialist

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohamadsaleh Peikar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Rasoul Ghasemian

Position

Hematology-Oncology Fellowship

Latest degree

Specialist

Other areas of specialty/work

Hematology

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Email

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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

only data related to main outcome will be shared.

When the data will become available and for how long

3months post published results

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

Analyzing the revealed data is not allowed.

From where data/document is obtainable

Rasoul Ghasemian, Isfahan Medical university
rasoolqasemian@yahoo.com

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

after e-mailing us, we send data.

Comments