

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial to compare the effectiveness of the granulocyte colony-stimulating factor with standard treatment in non-M3 acute myelogenous leukemia patients

Protocol summary

Study aim

To compare the effectiveness of the granulocyte colony-stimulating factor with standard treatment in non-M3 acute myelogenous leukemia patients.

Design

This randomized and single-blind clinical trial with parallel and control groups will be conducted on 81 patients who will be randomly selected using the blocks.

Settings and conduct

Non-M3 acute myelogenous leukemia patients referring to Imam Reza Hospital and Ghaem Hospital, Mashhad, Iran are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the granulocyte colony-stimulating factor and control will receive standard treatment. The person responsible for data collection is blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-M3 acute myelogenous leukemia patients have not received treatment; aged between 18 and 70 years. Exclusion criteria: Secondary acute myeloid leukemia patients; pregnant women with leukemia; patients with other malignancies; having cardiovascular disease; patients with Anaphylactic shock.

Intervention groups

The intervention group will receive 100-200 mg cytarabine for 7 days, 60-90 mg daunorubicin for 3 days and 300 µg granulocyte colony stimulating factor injection on the 8th day. The control group will receive 100-200 mg cytarabine for 7 days and 60-90 mg daunorubicin for 3 days.

Main outcome variables

Evaluation and comparison of the extinction of disease and one-year survival of patients in control and intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211219053451N1**

Registration date: **2021-12-23, 1400/10/02**

Registration timing: **prospective**

Last update: **2021-12-23, 1400/10/02**

Update count: **0**

Registration date

2021-12-23, 1400/10/02

Registrant information

Name

Mostafa Kamandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

khazaeia982@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of the granulocyte colony-stimulating factor with standard treatment in non-M3 acute myelogenous leukemia patients

Public title

The effectiveness of granulocyte colony-stimulating factor for treatment of non-M3 acute myelogenous leukemia patients.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Non-M3 acute myelogenous leukemia patients have not received treatment Aged between 18 and 70 years

Exclusion criteria:

Secondary acute myeloid leukemia patients Pregnant women with leukemia Patients with other malignancies Having cardiovascular disease Patients with Anaphylactic shock

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of block randomization. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Non-M3 acute myelogenous leukemia patients referring to Imam Reza Hospital and Ghaem Hospital, Mashhad,

Iran are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the granulocyte colony-stimulating factor and control will receive standard treatment. The person responsible for data collection is blind to group allocation and the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2021-06-15, 1400/03/25

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.204

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

Non-M3 acute myelogenous leukemia patients

ICD-10 code

C92.5

ICD-10 code description

Acute myelomonocytic leukemia

Primary outcomes**1****Description**

Extinction of disease

Timepoint

28 days after intervention

Method of measurement

Bone marrow biopsy

2

Description

One-year survival of patients

Timepoint

One year after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 100-200 mg cytarabine for 7 days, 60-90 mg daunorubicin for 3 days and 300 µg granulocyte colony stimulating factor injection on the 8th day.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive 100-200 mg cytarabine for 7 days and 60-90 mg daunorubicin for 3 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mostafa Kamandi

Street address

Imam Reza Hospital, Imam Reza Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

kamandim@mums.ac.ir

2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mostafa Kamandi

Street address

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0000

Email

kamandim@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mostafa Kamandi

Position

Hematology/oncology fellowship

Latest degree

Specialist

Other areas of specialty/work

Hematology

Street address

Imam Reza Hospital, Imam Reza Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

kamandim@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mostafa Kamandi

Position

Hematology/oncology fellowship

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Phone

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mostafa Kamandi

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable

Mostafa Kamandi provides the data analysis to the applicants via email: kamandim@mums.ac.ir

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

Applicants can send emails to him and receive a response within a week.

Comments