# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jul 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 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**
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**Postal code**
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**2**

**Recruitment center**
**Name of recruitment center**
Ghaem Hospital
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Mohsen Tafaghodi
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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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**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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**
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**Position**
Hematology/oncology fellowship

**Latest degree**
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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**