Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of the effect of arsenic trioxide adding to standard regimen 7-3 in acute myeloid leukemia patients: a Randomized single blind clinical trial

Protocol summary

Study aim

Evaluation of effect and superiority of Arsenic plus standard chemotherapy versus standard chemotherapy alone in induction of complete remission in acute myeloid leukemia (exept m3).

Design

Two arm parallel group consist of control and intervention group to evaluate superiority of Arsenic. sample size are 112 patients that randomized by person who not involved in treatment process. Superiority.

Settings and conduct

Single blind randomized trial for evaluation of effect of adding arsenic to standard chemotherapy in acute myeloid leukemia patients. A third person at an external site randomized patients between two group (A and B) to receive standard chemotherapy (A) and standard chemotherapy plus arsenic trioxide (B) . this study were done in academic state in one of the Tehran university of medical science hospital.

Participants/Inclusion and exclusion criteria

Newly Diagnosed primary non M3 AML, Age 15-59 years old

Intervention groups

control group receive Standard chemotherapy regimen consist of 7 days infusion cytarabine 100 mg /m2 + danourubicine 60 mg /m2 or for 3 days. intervention group receive Standard chemotherapy regimen as above + arsenic trioxide 0.15 m/kgfor 21 days.

Main outcome variables

Complete Remission (CR): Hematologic complete remission is defined as meeting all of the following response criteria for at least four weeks. < 5% blasts in the bone marrow; No blasts with Auer rods Normal maturation of all cellular components in the bone marrow No extramedullary disease (e.g., CNS, soft tissue disease) Neutrophils ≥ 1,000/µL Platelets ≥ 100,000/µL Transfusion independent

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N16**
Registration date: **2019-12-22, 1398/10/01**
Registration timing: **retrospective**

Last update: **2019-12-22, 1398/10/01**
Update count: **0**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation,Tehran University of Medic

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of arsenic trioxide adding to standard regimen 7-3 in acute myeloid leukemia patients: a Randomized single blind clinical trial

Public title
Effect of arsenic trioxide in induction of complete remission of acute myeloid leukemia(non m3)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with a newly diagnosis of AML according to the criteria of the WHO 2016 revision Age 15-59years Diagnosis of primary AML other than acute promyeloctic leukemia (AML M3), Adequate liver (serum bilirubin level < 2upper normal limit) and renal function test (serum creatinine <1.5upper normal limit or creatinine clearance >60) Normal cardiac function Females of childbearing age must have a negative serum pregnancy test ECOG <=2 Signed consent

Exclusion criteria:
Newly diagnosed patients older than age 60. CML in blastic crisis Patients with cardiopathies including recurrent supraventricular arrhythmia and any type of sustained ventricular arrhythmia or conduction block (A-V block grade II or III) Pregnant or breastfeeding women History of preexisting neurological disorders (seizure disorders) Patients with active second malignancy, excluding adequately treated basal or squamous cell carcinoma of the skin, or carcinoma in situ of the cervix

Age
From **15 years** old to **69 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into 2 study groups by balanced block randomization. The list of randomized patients is made by a person not involved in the study and then the participants are randomly assigned into treatment groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The computer gives each patient a code number. And the code numbers are then allocated to the treatment groups control(standard chemotherapy receiver) and intervention group(arsenic plus standard chemotherapy receiver). In this study, neither the participants nor the researchers know which participants belong to the placebo group, nor the intervention group. Only at the end of the study, the results are reported by a person not involved in the study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University Medical Sciences

Street address
Ethics Committee of Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran town.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2017-10-26, 1396/08/04

Ethics committee reference number
Ir.tums.medicine.rec.1396.4484

Health conditions studied

1

Description of health condition studied
Acute myeloid leukemia (non m3)

ICD-10 code
C92.0

ICD-10 code description
Acute myeloblastic leukemia

Primary outcomes

1

Description
Evaluation of effect of adding arsenic to standard chemotherapy on induction of complete remission of acute myeloid leukemia except m3

Timepoint
14 and 28 days after start of chemotherapy we performed bone marrow examination to evaluate remission rate.

Method of measurement
Bone marrow microscopic evaluation

Secondary outcomes

1

Description
overall survival
Timepoint
3 years after treatment completion
Method of measurement
follow up

2

Description
Disease free survival
Timepoint
3 years after treatment completion (1 - 2 months interval)
Method of measurement
follow up

3

Description
Arsenic Safty
Timepoint
within first 28 days
Method of measurement
Patient monitoring and Electrocardiography monitoring and laboratory tests

Intervention groups

1

Description
intervention group: received Standard chemotherapy regimen consists of 3 days of an anthracycline e.g daunorubicin at 60 mg/m2 and 7 days of cytarabine (100 mg/m2 continuous infusion) plus arsenic at 0.15 mg/kg for 21 days.
Category
Treatment - Drugs

2

Description
control group: received standard chemotherapy regimen consist of 7 days cytarabin at 100mg/m2 and 3 days daunorubicin at 60 mg/m2.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology, Oncology and stem cell transplantation rsearch center
Full name of responsible person
Mohammad Vaezi
Street address
Kargar shomali Ave., Shariati hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hematology, Oncology & Stem Cell Transplantation Research Center, Tehran University of Medical Sci.
Full name of responsible person
Asadollah Musavi
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hematology, Oncology & Stem Cell Transplantation Research Center, Tehran University of Medical Sci.
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
Hematology- Oncology and Stem Cell Transplantation

Research Center, Tehran University of Medical Sci

Full name of responsible person
Reza Manouchehri Ardekani

Position
Flowship of Hematology and Oncology

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

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Mohammad Vaezi

Position
Assistant Professor hematology and oncology

Latest degree
Subspecialist

Other areas of specialty/work
Hematology and medical oncology

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BSN

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available