Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 2026

Feasibility study of treatment of non promyelocytic acute myeloid leukemia in elderly patients by low dose cytozar plus Arsenic trioxide on ambulatory schedule

Protocol summary

Summary

Our purpose in this study is to explore the feasibility of treatment of non promyelocytic acute myeloid leukemia in elderly patients. We select ten patients with age further than 60 and treat by low dose cytozar subcutaneously plus arsenic trioxide for ten days in month. We will assess overall response rate and overall survival at the end of one year.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711061030N5**
Registration date: **2009-02-16, 1387/11/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-02-16, 1387/11/28

Registrant information

Name

Mahdi Jalili

Name of organization / entity

Hematology-Oncology & SCT Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2662

Email address

m_jalili@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2007-10-23, 1386/08/01

Expected recruitment end date

2008-02-20, 1386/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Feasibility study of treatment of non promyelocytic acute myeloid leukemia in elderly patients by low dose cytozar plus Arsenic trioxide on ambulatory schedule

Public title

Treatment of non promyelocytic acute myeloid leukemia in elderly patients by low dose cytozar plus Arsenic trioxide

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Elderly patients with non promyelocytic AML, Performance status (ECOG) 3 or 4 Exclusion criteria: Age <60 years old, AST or ALT more than ten times above normal, Serum billirubin above 5, Creatinine level>2

Age

From **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hematology-Oncology and SCT Research Center

Street address
Kargar Ave. Shariati Hospital

City
Tehran

Postal code
14114

Approval date
2008-03-18, 1386/12/28

Ethics committee reference number
418/ A / 7199

Health conditions studied

1

Description of health condition studied
Acute myeloid leukaemia

ICD-10 code
C92.0

ICD-10 code description
Acute myeloid leukaemia

Primary outcomes

1

Description
Response Rate

Timepoint
1, 2, 6 month and one year after intervention

Method of measurement
Bone Marrow Aspiration and Biopsy and complete blood count

Secondary outcomes

1

Description
Overal Survival

Timepoint
One year after intervention

Method of measurement
Survey of patients

Intervention groups

1

Description
Cytozar 20 mg /q12h/ sc/10d/q28d for 2 cycle

Category
empty

2

Description
Arsenic 10mg/infusion2h/iv/DW5% d1-d5,d7-d11

Category
empty

Recruitment centers

1

Recruitment center

Name of recruitment center
Hematology-Oncology and SCT Research Center

Full name of responsible person
Dr. Seyed Mehdi Hashemi

Street address
Kargar Ave. Shariati Hospital

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Masoud Yonesian

Street address
Tehran University of Medical Sciences

City
Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Hematology-Oncology and SCT Research Center

Full name of responsible person
Dr. Seyed Mehdi Hashemi

Position
Principal Investigator / Fellowship

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Dr. Mahdi Jalili

Position
Clinical Trials Unit secretary / MD

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty