

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Tehran University of Medical Sciences

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.

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

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

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

Overall 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
Street address
Kargar Ave. Shariati Hospital
City
Tehran
Postal code
14114
Phone
+98 21 8490 2635
Fax
+98 21 8800 4140
Email
horcbmt@sina.tums.ac.ir
Web page address
<http://horcsct.tums.ac.ir>

Person responsible for scientific 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
Street address
Kargar Ave. Shariati Hospital
City
Tehran
Postal code

14114
Phone
+98 21 8490 2635
Fax
+98 21 8800 4140
Email
horcbmt@sina.tums.ac.ir
Web page address
<http://horcsct.tums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity
Hematology-Oncology & SCT Research Center
Full name of responsible person
Dr. Mahdi Jalili
Position
Clinical Trials Unit secretary / MD
Other areas of specialty/work
Street address
Kargar Ave. Shariati Hospital
City
Tehran
Postal code
14114
Phone
+98 21 8490 2668
Fax
+98 21 8800 4041
Email
horcsct@yahoo.com
Web page address
<http://horcsct.tums.ac.ir>

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