

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The determination and comparison of plasma concentration of arsenic trioxide as intravascular and oral agent used in patients with Acute promyelocytic leukemia

Protocol summary

Summary

Purpose of this study is trying oral formulation (as capsule) of Arsenic instead of intravascular. Totally 10 patients with Acute promyelocytic leukemia type M3 and in complete remission treat with oral and intravascular arsenic trioxide. We determine plasma concentration of arsenic trioxide and calculate the Area Under the Curve(AUC) of Arsenic in both form of administration and compare them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710271030N4**

Registration date: **2009-03-09, 1387/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-03-09, 1387/12/19

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

Hematology-Oncology and SCT Research Center

Expected recruitment start date

2009-01-20, 1387/11/01

Expected recruitment end date

2009-04-20, 1388/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The determination and comparison of plasma concentration of arsenic trioxide as intravascular and oral agent used in patients with Acute promyelocytic leukemia

Public title

Arsenic trioxide as intravascular or oral agent used in patients with Acute promyelocytic leukemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Acute promyelocytic leukemia type M3, complete remission, not receiving any marine foods during last week, normal cardiopulmonary and renal function. Exclusion Criteria: Less than 16 years old, Impaired cardiopulmonary and renal function.

Age

From **16 years** old

Gender

Both

Phase

1-2

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

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hematology-Oncology and SCT Research Center
Ethics committee

Street address

Shariati Hospital, Kargar Ave.

City

Tehran

Postal code

14114

Approval date

2008-08-12, 1387/05/22

Ethics committee reference number

87/625/د ک

Health conditions studied

1

Description of health condition studied

Acute promyelocytic leukemia

ICD-10 code

C92.4

ICD-10 code description

Acute promyelocytic leukemia

Primary outcomes

1

Description

plasma concentration of arsenic trioxide

Timepoint

0,1,2,3,4,6,8,24,25,26,27,28,30,32,48h after initiation of therapy

Method of measurement

Atomic Absorption of Arsenic

Secondary outcomes

1

Description

side effects

Timepoint

During the study

Method of measurement

History taking and physical examination

Intervention groups

1

Description

At first day: Arsenic trioxide, 10 mg, capsule

Category

Treatment - Drugs

2

Description

At second day: Arsenic trioxide, 10 mg, infusion

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology-Oncology and SCT Research Center

Full name of responsible person

Aliarash Anoshiravani

Street address

Kargar Ave. Shariati Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hematology-Oncology & SCT Research Center

Full name of responsible person

Mojtaba Ramezani

Street address

Kargar Ave. Shariati Hospital

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hematology-Oncology & SCT Research Center

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*

Tehran

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Web page address<http://horcsct.tums.ac.ir>**Person responsible for updating data****Person responsible for general inquiries****Contact****Name of organization / entity**

Hematology-Oncology and SCT Research Center

Full name of responsible person

Aliarash Anoushiravani

Position

Principal Investigator / Fellowship

Other areas of specialty/work**Street address**

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Hematology-Oncology & SCT Research Center

Full name of responsible person

Dr. Mahdi Jalili

Position

Clinical Trials Unit secretary / MD

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Hematology-Oncology and SCT Research Center

Full name of responsible person

Aliarash Anoushiravani

Position

Principal Investigator / Fellowship

Other areas of specialty/work**Street address**

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City**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*