

# 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*

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**Postal code****Phone**

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anoush\_aa@yahoo.com

**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**

Kargar Ave. Shariati Hospital

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**Contact****Name of organization / entity**

Hematology-Oncology & SCT Research Center

**Full name of responsible person**

Dr. Mahdi Jalili

**Position**

Clinical Trials Unit secretary / MD

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**Person responsible for scientific 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**

Kargar Ave. Shariati Hospital

**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*