

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of Effect L-Arginine and intravenous fluid Therapy in Oligohydramnios

#### Protocol summary

##### Study aim

Comparison of Effect L-Arginine and intravenous fluid Therapy in Oligohydramnios.

##### Design

50 eligible pregnant women are randomly assigned into the two of intervention and control groups.

##### Settings and conduct

One-sided blind clinical trial in Fatemieh Hospital, Hamadan

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age between 28 to 36 weeks, Singleton pregnancy, AFI less than 8 cm  
Exclusion criteria: Pregnancy with anomalies, Diabetes, Severe preeclampsia, Preterm Premature Rupture of Membranes (PPROM)

##### Intervention groups

Intervention group 1: L-arginine at a dose of 3 grams twice a day with oral fluid therapy or, if possible (not suffering from gestational hypertension), 3 liters of injectable lactate ringer in 24 hours. Intervention group 2: Liquid therapy orally 10 to 15 glasses (100 cc) or 3 liters of injectable ringer lactate in 24 hours

##### Main outcome variables

Primary outcome: Amniotic fluid index  
Secondary outcome: gestational age at delivery; ; fetal weight, APGAR Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160523028008N5**  
Registration date: **2020-12-15, 1399/09/25**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

##### Registration date

2020-12-15, 1399/09/25

##### Registrant information

###### Name

Mohammad Faryadras

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3428 9706

###### Email address

m.faryadras@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2021-01-20, 1399/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Effect L-Arginine and intravenous fluid Therapy in Oligohydramnios

##### Public title

Effect L-Arginine and intravenous fluid Therapy in Oligohydramnios

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Gestational age between 28 and 36 weeks Single

pregnancy AFI less than 8 cm

**Exclusion criteria:**

Pregnancy with anomalies Diabetes Severe preeclampsia  
Preterm Premature Rupture of Membranes (PPROM)

**Age**

No age limit

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **25**

25 subject for each group

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomly assigned to the intervention and control groups using block randomization The patients will be randomly assigned to the intervention and control groups using block randomization Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number (between 1 and 6 ) to each of them 3)Choosing random numbers between 1 and 6 4) Defining the treatment assignment list

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

the statistical analyser will be unaware of the type of intervention performed in the groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Research Ethic Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor of Research the Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2020-05-09, 1399/02/20

**Ethics committee reference number**

IR.UMSHA.REC. 1399.149

**Health conditions studied**

**1**

**Description of health condition studied**

Oligohydramnios

**ICD-10 code**

O41.0

**ICD-10 code description**

Oligohydramnios

**Primary outcomes**

**1**

**Description**

Amniotic fluid index

**Timepoint**

One week after the intervention for up to 4 weeks

**Method of measurement**

Ultrasonography

**Secondary outcomes**

**1**

**Description**

Neonatal Apgar score

**Timepoint**

At 1 and 5 minutes after birth

**Method of measurement**

Data sheets

**2**

**Description**

Neonatal weight

**Timepoint**

At birth

**Method of measurement**

Data sheets, gram

**3**

**Description**

Gestational Age at birth

**Timepoint**

At the end of the study

**Method of measurement**

Data sheets

**Intervention groups**

## 1

### Description

Intervention group: L-arginine at a dose of 3 grams twice a day with oral fluid therapy or, if possible (not suffering from gestational hypertension), 3 liters of injectable lactate ringer in 24 hours.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Liquid therapy orally 10 to 15 glasses (100 cc) or 3 liters of injectable ringer lactate in 24 hours.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Fatemieh Hospital

#### Full name of responsible person

Shahla Nasrolahi

#### Street address

Fatemieh Hospital, Pasdaran Ave.

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3838 0717

#### Email

Dr-nasrolahi@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr Saeid Bashirian

#### Street address

Vice-chancellor of Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3838 0717

### Email

Dr-nasrolahi@yahoo.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Hamedan University of Medical Sciences

### 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

Hamedan University of Medical Sciences

#### Full name of responsible person

Shahla Nasrolahi

#### Position

Associate Professor of Perinatology

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Fatemieh Hospital, Pasdaran Ave.

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3838 0717

#### Email

Dr-nasrolahi@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Shahla Nasrolahi

#### Position

Associate Professor of Perinatology

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

Dr-nasrolahi@yahoo.com

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

Dr-nasrolahi@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Shahla Nasrolahi

**Position**

Associate Professor of Perinatology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

**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