

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 inject able lactate ringer in 24 hours. Intervention group 2: Liquid therapy orally 10 to 15 glasses (100 cc) or 3 liters of inject able 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 ring in 24 hours.

Category

Treatment - Drugs

2

Description

Intervention group: Liquid therapy orally 10 to 15 glasses (100 cc) or 3 liters of injectable ring 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

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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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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