Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effect of intravenous fluid therapy on amniotic fluid index in oligohydramnios.

Protocol summary

Study aim

1.Determination of the effect of intravenous fluid therapy on amniotic fluid index in oligohematerialis.
2.Comparison of the mean of amniotic fluid index before and after intravenous fluid therapy in mothers with oligohydramnios.

Design

Firstly, women of the age group of 35 or more gestational age who are willing to participate in the research with a written consent and who have the characteristics of the research unit are selected and embedded in the experimental group. Each mother in the study will receive 3000 ml of Ringer serum within 24 hours. 48 hours after administration of intravenous fluid therapy, sonography is performed to determine the amniotic fluid index for mother. The present study does not have control group.

Settings and conduct

Firstly, oligohydramnios women with a gestational age of 35 weeks or more who were referred to Iran Hospital of Iranshahr are selected and embedded in the experimental group.In the experimental group, the study will receive 3000 milligrams of Ringer serum within 24 hours. For 48 hours after administration of intravenous fluid therapy, sonography is performed to determine the amniotic fluid index for both groups. Blinding was performed for data analyzers. .

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Single pregnancy; Intact Amniotic Sac; gestational age greater than or equal to 35 weeks; amniotic fluid index less than or equal to 5 cm. EXclusion Criteria: Normal Amniotic Fluid index; Polyhydramnios.

Intervention groups

In the intervention group, each mother will receive 3000 ml of Ringer serum within 24 hours. After 48 hours of intravenous fluid administration, sonography is performed to determine the amniotic fluid index. The present study does not have control group.

Main outcome variables

Amniotic fluid index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160418027464N3**
Registration date: **2019-05-14, 1398/02/24**
Registration timing: **prospective**

Last update: **2019-09-22, 1398/06/31**
Update count: **1**

Registration date

2019-05-14, 1398/02/24

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 37212968054

Email address

dr.azarkish@irshums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-18, 1398/02/28

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of intravenous fluid therapy on amniotic fluid index in oligohydramnios.

Public title
Effect of Intravenous hydrotherapy on "Ammonium fluid reduction"
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Single pregnancy Intact Amniotic fluid Gestational age greater than or equal to 35 weeks Amniotic fluid index less than or equal to 5 cm.
Exclusion criteria:
Normality of the amniotic fluid index. Polyhydramnios Twin Pregnancy
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
The study design was a quasi-experimental clinical trial without control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iranshahr University of Medical Sciences
Street address
Balouch street
City
Iranshahr
Province
Sistan-va-Balouchestan
Postal code
99157-19444
Approval date
2015-10-25, 1394/08/03
Ethics committee reference number
IR.IRSHUMS.REC.1394.11

Health conditions studied

1

Description of health condition studied
Oligohydramnios
ICD-10 code
O41.9
ICD-10 code description
Disorder of amniotic fluid and membranes, unspecified

Primary outcomes

1

Description
Amniotic fluid index.
Timepoint
48 hours after intervention.
Method of measurement
Sonoghraphy

Secondary outcomes

1

Description
Amniotic Fluid Index.
Timepoint
48 hours after intervention.
Method of measurement
sonography.

2

Description
Apgar the first minute
Timepoint
Immediately after childbirth
Method of measurement
Newborn Clinical Examination

Intervention groups

1

Description
Intervention group: In the experimental group, the study will receive 3000 cc of Ringer serum within 24 hours and will be performed in the routine care control group for oligohematerial patients. 48 hours after administration of intravenous fluid therapy, sonography was performed to determine the amniotic fluid index for the group. It will be
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Iranshahr Hospital
Full name of responsible person
Fatemeh Azarkish
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Iranshahr 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
Iranshahr University of Medical Sciences
Full name of responsible person
Fatemeh Azarkish
Position
Assistant Professor
Latest degree
Ph.D.
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Midwifery
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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
It is not necessary.
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