Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The effect of oral and intravenous maternal hydration in third trimester of pregnancy on increasing the amniotic fluid index

Protocol summary

Summary

Oligohydramnios is the volume of amniotic fluid that is lower than the expectance for pregnancy age and if it will be higher than normal, it will cause to abnormality of fetal, compression of cord and finally death. The purpose of this study is to determine the effect of oral and intravenous fluid therapy by hypotonic liquid for pregnant women with partial oligohyramnios and study changes of amniotic fluid volume in these groups before and after treatment. This clinical study was done in 60 pregnant women between 35 to 38 weeks of pregnancy that had amniotic fluid index between 5 to 10 c.m with normal amniotic bag and fetus without any abnormality in sonography. They were divided in 3 groups. First group did not receive any treatment and were as control group, the second group treated by oral hydration with 2L\2 h and finally the third group treated by intravenous hypotonic liquid (ringer) with 2L\2 h. Before and 1 hour after treatment sonography was done and AFI was calculated.

General information

Acronym

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IRCT registration information

IRCT registration number: **IRCT201102203820N2**
Registration date: **2011-04-08, 1390/01/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-08, 1390/01/19

Registrant information

Name

Zinatalsadat Bouzari

Name of organization / entity

Babol university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and technology, Babol University of Medical Sciences

Expected recruitment start date

2008-05-21, 1387/03/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral and intravenous maternal hydration in third trimester of pregnancy on increasing the amniotic fluid index

Public title

The effect of liquid treatment on increasing the amniotic fluid

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Amniotic fluid index 5-10 cm, Amniotic membrane intact, age of Pregnancy 35-36 week, Normal fetus. Exclusion criteria: Toxemia of pregnancy, patients with previous gestational diabetes, cardiovascular disease, hyperthyroidism, fetus with congenital defect.

Age
From **16 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice Chancellor for Research and technology, Babol University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Gangafroz Avenue
City
Babol
Postal code
Approval date
2008-07-21, 1387/04/31
Ethics committee reference number
842

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
Before treatment and 1 h after treatment
Method of measurement
sonography

Secondary outcomes

empty

Intervention groups

1

Description
First group: is control group and did not receive any treatment
Category
N/A

2

Description
Second group: was treated by oral hydration with 2L\2 h (water)
Category
Other

3

Description
Third group: was treated by intravenous hypotonic liquid (ringer) with 21\2 h
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol Yahiianejad Hospital
Full name of responsible person
Dr. Maryam Javadian Kotenae
Street address
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and technology, Babol University of Medical Sciences
Full name of responsible person
Dr. Ali Bijani
Street address
Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Gangafroz Avenue

City
Babol
Grant name
.
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and technology, Babol University of Medical Sciences
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

Person responsible for general inquiries

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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