

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

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

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 4651

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z_b412003@yahoo.com

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**

Babol

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

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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

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr. Zinatossadat Bouzari

Position
Assistant professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity
Fatemehzahra Fertility & reproductive Health Research Center

Full name of responsible person
Nargess Gholizadeh Pasha

Position
M.A./Responsible for Public Affairs Research Center

Other areas of specialty/work

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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