Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Effect of intravenous hydration on amniotic fluid index and outcomes of pregnancy in term pregnancy and oligohydramnios

Protocol summary

Summary

Aim of this Randomized controlled trial is to examine the effect of intravenous hydration on amniotic fluid index and outcomes of pregnancy in term pregnancy and oligohydramnios. Our target population is pregnant women(37-42week) reffer to clinic of hospital. JAVA software was used to determine sample size. 10 patients were randomized to the hydration group and 10 to the no hydration group. inclusion criteria: pregnant women with intact of membrane with low fluid index below and equal the 5; single pregnancy; cephalic presantation; with no heart, lung and renal disorder; inactive labor; Reative NST; no fetus complication. After getting written informed consent , Patients in the hydration group will be given a 1 L IV fluid bolus of isotonic serum over a period of 30 minutes. One hour after the completion of the bolus, the AFI measurement will repeat. In the no hydration group, the repeat AFI measurement will perform 90 minutes after the initial examination. Finally outcomes of pregnancy will compare with two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112146709N7**
Registration date: **2012-04-08, 1391/01/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-08, 1391/01/20

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

mshahnazi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy, Tabriz University of Medical Sciences

Expected recruitment start date

2012-01-30, 1390/11/10

Expected recruitment end date

2012-08-20, 1391/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous hydration on amniotic fluid index and outcomes of pregnancy in term pregnancy and oligohydramnios

Public title

Effect of hydration on amniotic fluid volume and outcomes of pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational age (37-42W); intact of membrane with low fluid index below and equal the 5; single pregnancy; cephalic presantation; with no heart , lung, renal disorder, hypertantion and hemorrhage; inactive labor; Reative NST ; there is not complication of fetus and placenta and uterus (IUGR. myoma). Exclusion criteria: withdrew from continuing the

research
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
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
Tabriz University of Medical Sciences
Street address
Golgasht street , Tabriz
City
Tabriz
Postal code
51665118
Approval date
2011-12-31, 1390/10/10
Ethics committee reference number
8661

Health conditions studied

1

Description of health condition studied
Oligohydramnios
ICD-10 code
041.0
ICD-10 code description
Oligohydramnios without mention of rupture of membranes

Primary outcomes

1

Description
Aminiotic Fluid Index
Timepoint
Baseline AFI will measure and will repeat 90 minutes later
Method of measurement
Sonography

Secondary outcomes

1

Description
Fetal Heart Rate
Timepoint
During of labour
Method of measurement
External monitoring

2

Description
Meconium- Stained amniotic fluid
Timepoint
During of labour
Method of measurement
Observational cheklist

3

Description
Kind of delivery
Timepoint
Time of delivery
Method of measurement
Observational cheklist

Intervention groups

1

Description
In intervention group will be given a 1 L IV fluid bolus of isotonic serum over a period of 30 minutes.
Category
Treatment - Drugs

2

Description
any intervention will not be done In the control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Alzahra Teaching- Cure Hospital
Full name of responsible person
Shanazi- Mahnaz
Street address
Baghshomal square , Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Golgasht street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy, Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Shanazi- Mahnaz
Position
MSC in Midwifery
Other areas of specialty/work
Street address
South Shariati street,Faculty of Nursing and Midwifery
City
Tabriz
Postal code
347-51745
Phone
+98 41 1479 6770
Fax
+98 914 300 2433
Email
mshahnazi@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz Univercity of Medical Sciences
Full name of responsible person
Shanazi- Mahnaz
Position
MSC in Midwifery
Other areas of specialty/work
Street address
South Shariati street , Faculty of Nursing and Midwifery
City
Tabriz
Postal code
347-51745
Phone
+98 41 1479 6770
Fax
+98 47 96969
Email
mshahnazi@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Shanazi- Mahnaz
Position
MSC in Midwifery
Other areas of specialty/work
Street address
South Shariati street, Faculty of Nursing and Midwifery
City
Tabriz
Postal code
347-51745
Phone
+98 41 1479 6770
Fax
+98 47 96969
Email
mshahnazi@tbzmed.ac.ir
Web page address

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