

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) refer 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 presentation; 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

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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 presentation; 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
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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