

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Effect of intravenous hydration on amniotic fluid index in women with preterm premature rupture of membrane referring to Alzahra teaching hospital-tabriz-2010-11

Protocol summary

Summary

Aim of this Randomized controlled trial is to examine the effect of intravenous hydration on amniotic fluid index in the pregnant women with preterm premature rupture of membrane. Our target population is pregnant women (28-34 week) with complaint of leakage and rupture of membrane that refer to clinic of hospital. JAVA software was used to determine sample size. 12 patients were randomized to the hydration group and 12 to the no hydration group. Inclusion criteria: pregnant women with rupture of membrane with low fluid index below and equal the 5; single pregnancy; cephalic presentation; with no heart and lung and renal disorder; inactive labor; Reactive NST; no fetus complication; duration of rupture lower than 48 h; no clinical chorioamnionitis. Patients in the hydration group will be given a 1 L IV fluid bolus of isotonic serum over a period of 30 minutes. One and 48 hours after the completion of the bolus, the AFI measurement will repeat. In the no hydration group, the repeat AFI measurement will perform 90 minutes and 48 hours after the initial examination. Primary outcomes are increasing the amniotic fluid index and longer time interval from the fluid bolus to delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106066709N1**
Registration date: **2011-08-21, 1390/05/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-21, 1390/05/30

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2011-06-14, 1390/03/24

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous hydration on amniotic fluid index in women with preterm premature rupture of membrane referring to Alzahra teaching hospital-tabriz-2010-11

Public title

Effect of hydration on AFI

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational age

(28-34W); rupture of membrane with low fluid index below and equal the 5; single pregnancy; cephalic presentation; with no heart and lung and renal disorder, hypertension and hemorrhage; inactive labor, Reactive NST ; there is not complication of fetus and placenta and uterus (IUGR, myoma); duration of rupture lower than 48 h; no clinical chorioamnionitis. 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: **24**

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

Research Deputy, Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

51665118

Approval date

2011-06-02, 1390/03/12

Ethics committee reference number

909

Health conditions studied

1

Description of health condition studied

Preterm Premature Rupture Of Membrane

ICD-10 code

042

ICD-10 code description

Premature Rupture Of Membranes

Primary outcomes

1

Description

Aminiotic Fluid Index

Timepoint

Basement, 90 min, 48 h

Method of measurement

Sonography

Secondary outcomes

1

Description

Time to delivery

Timepoint

From basement measure to delivery

Method of measurement

Clock

Intervention groups

1

Description

In interference 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 Hospital

Full name of responsible person

Hajizadeh- Khadijeh, student of MSC in Midwifery

Street address

Baghshomal square

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Research deputy, Tabriz University of Medical Sciences, Golgasht Ave

City

Tabriz

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, 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-Faculty of Nursing and Midwifery Tabriz

Full name of responsible person

Hajizadeh- Khadijeh

Position

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Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

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Position

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Other areas of specialty/work**Street address**

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Web page address**Person responsible for updating data****Contact****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