

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The effect of hydrotherapy on labor and delivery process in Alzahra teaching hospital

#### Protocol summary

##### Summary

Aim of this randomized controlled trial is to examine the effect of hydrotherapy on labor and delivery process in Alzahra teaching hospital. Our target population is pregnant women that after entering the delivery room and completion of primary clinical examination assess for eligibility. Inclusion criteria: single pregnancy; cephalic presentation; no heart and lung and renal disorder, hypertension, diabetes; there is not complication of fetus (IUGR, oligohydramnios, anomaly); the head of fetus enters in the pelvic. JAVA software was used to determine sample size. 50 patients were randomized to the control group and 50 to the interference group. Pregnant women in the active phase of labor take a warm shower about two times and each time for 30 minutes. Collecting data measure on the NRS pain scale at 4.6.8.10 dilatation. Duration of the first and second stage of labor is determined on the base of partograph. In this study primary outcomes are decreasing the labor pain, decreasing the mean duration of the first and second stage of labor and increasing APGAR score. ABG analyze on the base of umbilical artery PH, BE.

#### General information

##### Acronym

Hydrotherapy

##### IRCT registration information

IRCT registration number: **IRCT201110017676N1**

Registration date: **2015-02-03, 1393/11/14**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-02-03, 1393/11/14

##### Registrant information

##### Name

Simin Taghavi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1553 9161

##### Email address

taghavi@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2015-02-08, 1393/11/19

##### Expected recruitment end date

2015-05-22, 1394/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of hydrotherapy on labor and delivery process in Alzahra teaching hospital

##### Public title

The effect of hydrotherapy

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: single pregnancy; cephalic presentation; no heart and lung and renal disorder, hypertension, diabetes; there is not complication of fetus (IUGR, oligohydramnios, anomaly); the head of fetus enters in the pelvic. Exclusion criterion: withdrew from

continuing the research.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **100**

**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**

Tabriz University of Medical Sciences, Golgash Ave

**City**

Tabriz

**Postal code**

51665118

**Approval date**

2009-06-13, 1388/03/23

**Ethics committee reference number**

5/4/2541

**Health conditions studied****1****Description of health condition studied**

Delivery

**ICD-10 code**

O80.0

**ICD-10 code description**

Spontaneous vertex delivery

**Primary outcomes****1****Description**

Pain

**Timepoint**

At the Dilatations 4, 6, 8 and 10 cm

**Method of measurement**

NRS scale

**Secondary outcomes****1****Description**

Duration of labor

**Timepoint**

Active labor until cervix is dilated to 10 cm, cervix is dilated until delivery of infant

**Method of measurement**

Partograph

**2****Description**

APGARscore

**Timepoint**

In 1,5 minutes

**Method of measurement**

Activity,Pulse,Grimace,Appearance,Respiration

**3****Description**

ABG(arterial blood gass)

**Timepoint**

Post delivery

**Method of measurement**

Umbilical Artery PH, Umbilical Artery BE

**Intervention groups****1****Description**

pregnant women in the intervention group in the active phase of labor take a warm shower about two times and each time for 30 minutes

**Category**

Other

**2****Description**

Any intervention will not be done in the control group

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Alzahra Teaching Hospital

**Full name of responsible person**

Dr. Pouya Khadijeh, Residency of Ob & Gyn

**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

**Full name of responsible person**

Dr. Pouya Khadijeh

**Position**

Residency of Ob & Gyn

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Taghavi Simin

**Position**

Associated prof of Ob & Gyn, fellowship of perinatology

**Other areas of specialty/work**

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## Person responsible for updating data

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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*