

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**comparison of "nutrition, bath and anointment" as a package in Iranian traditional medicine with current method in pregnant women on duration of active phase of labour.**

### Protocol summary

#### Summary

(1) Objectives: This clinical trial has been designed to compare the effect of "nutrition, bath and anointment" as a package in Iranian traditional medicines with current method on labour. (2) Design: This study is a phase 3 clinical trial, randomized, not blind, with 36 people in each group. (3) Setting and conduct: The study population are pregnant women at 33-38 weeks of pregnancy who refer to obstetrician clinic of Akbarabadi hospital in Tehran. They are randomized divided into case and control groups. Then instructions are taught to intervention group. (4) Participants are 18-35 years old pregnant women; single gestation with cephalic presentation; primigravida; preclusion of normal vaginal delivery with no history of infertility; internal or surgical disease; smoking or addiction; pregnancy disorder like vaginal bleeding, fetal distress and etc. (5) Intervention: Instruction are three groups which are taught to intervention group. Diet, bath and anointment should be used from 38 week of pregnancy and be continued up to end of pregnancy. They should stop eating sour food and diet which causes constipation and eat chicken soup once a day. They should take a bath with warm water including abdomen in ten minutes once a day and then anoint the lumbar area, abdomen, suprapubic and groin with sesame oil. The control group receive the usual obstetrician care. (6) Main outcome: After delivery information of labour progression, post term labour, duration of different phases of labour, techniques and drugs which used in labour process, type of delivery, neonate apgar and satisfaction will be collected.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2012111811505N1**

Registration date: **2013-06-15, 1392/03/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2013-06-15, 1392/03/25

#### Registrant information

##### Name

Yasaman Vazani

##### Name of organization / entity

Faculty of Traditional Medicine, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5569 3520

##### Email address

y-vazani@razi.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

#### Expected recruitment start date

2012-12-21, 1391/10/01

#### Expected recruitment end date

2013-07-23, 1392/05/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

comparison of "nutrition, bath and anointment" as a package in Iranian traditional medicine with current method in pregnant women on duration of active phase of labour.

**Public title**

comparison of "nutrition, bath and anointment" as a package in Iranian traditional medicine with current method on labour.

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

inclusion criteria: age 18-35 years old; single gestation with cephalic presentation; primigravida; prevision of normal vaginal delivery. exclusion criteria: history of infertility; any internal or surgical disease; smoking or addiction; pregnancy disorder like vaginal bleeding, fetal distress, fetal death and etc.

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of the Research Institute for Islamic and Complementary Medicine, Tehran University

**Street address**

No. 9, Pirnia Alley, Lalehzar St., Jomhury Ave., Tehran, Iran

**City**

Tehran

**Postal code****Approval date**

2012-11-12, 1391/08/22

**Ethics committee reference number**

846\26پ م ط

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

delivery facilitation

**ICD-10 code**

O80.0

**ICD-10 code description**

Spontaneous vertex delivery

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

duration of active phase of labour

**Timepoint**

during labour

**Method of measurement**

physical exam

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

gestational age at the time of delivery

**Timepoint**

labour time

**Method of measurement**

history

**2****Description**

labour pain

**Timepoint**

after delivery

**Method of measurement**

pain ruler

**3****Description**

duration of second stage of labour

**Timepoint**

during labour

**Method of measurement**

physical exam

**4****Description**

type of delivery

**Timepoint**

after delivery

**Method of measurement**

observation

## 5

**Description**

using oxytocin

**Timepoint**

during labour

**Method of measurement**

observation

## 6

**Description**

satisfaction

**Timepoint**

after delivery

**Method of measurement**

questioner

## 7

**Description**

apgar

**Timepoint**

first and fifth minute after birth

**Method of measurement**

physical exam

## 8

**Description**

first time of breast feeding

**Timepoint**

after delivery

**Method of measurement**

observation

## 9

**Description**

time of meconium passing

**Timepoint**

after delivery

**Method of measurement**

observation

## **Intervention groups**

### 1

**Description**

control group:no intervention

**Category**

N/A

### 2

**Description**

intervention group:The instruction are taught verbal and written.Instruction are three groups. Diet; bath and anointment should be used from 38 weeks of pregnancy and be continued up to end of pregnancy.They should stop eating sour food and diet which causes constipation(cow and calf meat, conserved food,

mushroom, date, lenti, cabbage, eggplant, macaroni, spaghetti soup, kallepache, haleem) and eat chicken soup including chicken, rice, coriander once a day. They should take a bath with warm water including abdomen ten minutes once a day and then anoint the lumbar area, abdomen, supra pubic and groin with sesame oil.

**Category**

Lifestyle

## **Recruitment centers**

### 1

**Recruitment center****Name of recruitment center**

Akbarabadi hospital

**Full name of responsible person**

Yasaman Vazani

**Street address**

Baghe Ferdos station, Molavi Ave., Tehran, Iran

**City**

Tehran

## **Sponsors / Funding sources**

### 1

**Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotuhi

**Street address**

Vice chancellor for research, Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd., Tehran, Iran

**City**

Tehran

**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, Tehran 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**

Faculty of Traditional Medicine, Tehran University of  
Medical Sciences

**Full name of responsible person**

Yasaman Vazani

**Position**

Ph.D. student in Traditional Medicine

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

Faculty of Traditional Medicine, Behesht St., Vahdate  
Eslami Ave., Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 5569 3520

**Fax****Email**

y-vazani@razi.tums.ac.ir

**Web page address****Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Traditional Medicine, Tehran University of  
Medical Sciences

**Full name of responsible person**

Yasaman Vazani

**Position**

Ph.D. student in Traditional Medicine

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

Faculty of Traditional Medicine, Behesht St., Vahdat  
Eslami Ave., Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 5569 3520

**Fax****Email**

y-vazani@razi.tums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Akbarabadi hospital

**Full name of responsible person**

Maryam Kashanian

**Position**

gynecologist and obstetrician

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

Baghe Ferdos station, Molavi Ave., Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 5562 4197

**Fax****Email**

maryamkashanian@yahoo.com

**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*