

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

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Iran (Islamic Republic of)

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+98 21 5569 3520

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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
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Full name of responsible person

Yasaman Vazani

Position

Ph.D. student in Traditional Medicine

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

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

Akbarabadi hospital

Full name of responsible person

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Position

gynecologist and obstetrician

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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