Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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; prevision 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

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yasamanv77@yahoo.com

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\26\م ط\پ

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
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Ph.D. student in Traditional Medicine
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Akbarabadi hospital
Full name of responsible person
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gynecologist and obstetrician
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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