Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology on anxiety, pain and outcomes of labor in primiparus woman referred to the Karaj hospital in 2011

Protocol summary

Summary

The aim of this study is to determine the effect of foot reflexology on anxiety, pain and labor outcomes in primiparous women. This study is randomized controlled trial, one-blind and multi-center with two groups. The study populations include primiparous women with singleton term pregnancies with cephalic presentation and without any medical problems or pregnancy complications. They don't use any drug or method of analgesia and anesthesia and labor induction. The sample include 50 patients (two groups of 25 persons) will be randomly allocated into the following two group: experimental group (foot reflexology) and control group (routine care). Intervention in reflexology group is consist gentle massage of plantar and then continuous pressure on solar network, pituitary and uterus points in the feet for 40 minutes (20 minutes per foot) at 3-4 cm dilatation. For the control group will be done routine care and massages of other parts of foot. Assessment of pain in the first stage of labor will be done in 3-4cm cervical dilatation, immediately after intervention and also the half-intervals, one and two hours after the intervention in two groups according to the McGill Pain index. Immediately after the intervention, Spielberger Anxiety Inventory is completed for intervention and control groups. Duration of the first, second and third stages of labor, type of delivery and neonatal Apgar score at 1 and 5 minutes after birth in both groups will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103015948N1**
Registration date: **2011-06-24, 1390/04/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-24, 1390/04/03

Registrant information

Name
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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad University of karaj branch

Expected recruitment start date

2011-06-08, 1390/03/18

Expected recruitment end date

2011-09-09, 1390/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on anxiety, pain and outcomes of labor in primiparus woman referred to the Karaj hospital in 2011

Public title

The effect of foot reflexology on labor outcome

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Women with singleton pregnancies and fetal with cephalic presentation, gestational age 37-41 weeks, without active psychiatric disorders and anxiety on personality according to Beck and Spielberger questionnaires, without mental retardation, blindness and deafness, absence of fever, seizures, thrombosis, renal or gallbladder stones, foot disease, swelling, ulcer, trauma and fractures in the foot, not using the anti-anxiety medications and methods of complementary medicine during the previous week. Exclusion criteria: Use of any drug or method of analgesia and anesthesia, induction of labor with Oxytocin, abnormal fetal heart patterns, presence of any special medical condition (e.g. chronic diseases) and nature of taking any drug, women with a history of abortion, gestational hypertension, presence of any abnormal bleeding from placental abruption or placenta previa, polyhydroamnious, oligohydroamnious and intrauterine growth restriction that proved by ultrasound method, passing more than 12 hours from the time of rupture of membrane.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
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
Ethics Committee of Islamic Azad university Karj barnch
Street address
Crossroad of Moazen Blv and Esteghlal Blv, Rajaeeshahr, Karaj, Mailbox: 31485-313
City
Karaj
Postal code
Approval date
2011-06-07, 1390/03/17
Ethics committee reference number
0022

Health conditions studied

1

Description of health condition studied
Labor outcomes
ICD-10 code
O80-O84
ICD-10 code description
Delivery

Primary outcomes

1

Description
Labor pain intensity
Timepoint
Before intervention in 3-4cm cervical dilatation and immediately, half, one and two hours after the intervention
Method of measurement
McGill pain questionnaire

2

Description
Anxiety score
Timepoint
Before intervention in 3-4cm cervical dilatation and immediately after the intervention
Method of measurement
Spielberger anxiety inventory

3

Description
Duration of the first stage of labor
Timepoint
One time the start of labor until complete effacement and cervical dilatation
Method of measurement
According to minutes using the standard digital clock

4

Description
Duration of the second stage of labor
Timepoint
One time from full dilatation of cervix to departure of baby
Method of measurement
According to minutes using the standard digital clock

5

Description
Duration of the third stage of labor

Timepoint
One time from departure of baby to complete withdrawal of placenta
Method of measurement
According to minutes using the standard digital clock

Secondary outcomes

1

Description
Type of delivery
Timepoint
One time after departure of baby
Method of measurement
Observed as a vaginal delivery, instrumental delivery and cesarean section

2

Description
Apgar score
Timepoint
At 1 and 5 minutes after birth
Method of measurement
Observation and examination

Intervention groups

1

Description
For intervention group: Gentle massage of all surface of plantar and some points upon of feet using thumb and pointing fingers then continuous pressure on solar network, pituitary and uterus points in the feet for 40 minutes (20 minutes per foot) at 3-4 cm dilatation. The point of solar network is located on the border of one-third upper and middle feet (in part that wrinkle is formed during the foot plantar flexion) along the second and third finger. Pituitary point is located in the middle of toe. Uterine point also is located into the deep area between internal ankles and heel of feet.
Category
Other

2

Description
For control group: Receiving routine care of labor ward and massages of other parts of foot except three main points that mentioned, for 40 minutes (20 minutes per foot) at 3-4 cm dilatation.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alborz hospital
Full name of responsible person
Zahra Mehdizadeh Toorzani
Street address
Alborz hospital, Parastar Blv, Western Baghestan, Mianjadeh, Karaj
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2

Recruitment center
Name of recruitment center
Specialized Bahonar hospital
Full name of responsible person
Soheila Moghimi Hanjani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Islamic Azad University of Karaj branch
Full name of responsible person
Dr. Abas Ahmadi
Street address
Vice chancellor for research, Islamic Azad University of Karaj branch, Crossroad of Moazen Blv and Esteghlal Blv, Rajaeeshahr, Karaj
City
Karaj
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, Islamic Azad University of Karaj branch
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

Islamic Azad University Karaj branch

Full name of responsible person

Soheila Moghimi Hanjani

Position

Master of midwifery

Other areas of specialty/work

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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