

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

Soheila Moghimi Hanjani

Name of organization / entity

Islamic Azad University Karaj Branch

Country

Iran (Islamic Republic of)

Phone

+98 21 7720 4224

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soheila.moghimi@kiaau.ac.ir

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, Mianjاده, Karaj

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Karaj

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

Specialized Bahonar hospital

Full name of responsible person

Soheila Moghimi Hanjani

Street address

Specialized Bahonar hospital, Azimieh three-way, Karaj

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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

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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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Email

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