Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of acupressure at SP6 point and foot reflexology on severity of labor pain and duration in the first stage of labor

Protocol summary

Summary

Childbirth is arguably one of the most painful experiences women undergo during their lives. This study aimed to compare and recognize the effect of acupressure on the SP6 point and foot reflexology on the intensity of labor pain and the duration of the first stage of labor. Akbar Abadi Hospital in Tehran is chosen as the location of sampling. A total 106 pregnant women in labor will randomly divided into acupressure (35), reflexology (35) and routine care groups (36). Inclusion criteria are primigravid and second birth multigravid women; Iranian race; aged 18 to 35 years old; gestational age of 37 to 42 weeks and absence of chronic diseases. Exclusion criteria include: Caesarean section for any reasons. Acupressure on the SP6 point and reflexology on the solar plexus point (kidney 1) and uterus zone will perform. Mothers in the routine care groups receive routine care. In order to eliminate the effects of psychological support from the presence of researcher, also this group receives a placebo point touch (dorsal region of the foot along with third and fourth finger which is not any pathway meridians). Reflexology and acupressure groups receive interventions in 4 to 5 and 7 to 8 cm cervical dilatation in two 30 min (2 min pressure and 1 min break) on the mentioned points by the researcher. The main outcomes are included pain intensity and duration of the first stage of labor. The intensity of pain record by visual analogue scale (0 to 10 cm) and duration of the first stage measure with Swatch Swiss watch.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311136807N9**
Registration date: **2014-09-27, 1393/07/05**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-09-27, 1393/07/05

Registrant information

Name
Sedigheh Amir Ali Akbari
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2272 9240
Email address
akbarisedd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Obstetrics department, Valiasr St, Tehran

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of acupressure at SP6 point and foot reflexology on severity of labor pain and duration in the first stage of labor

Public title

Comparing the effect of acupressure at SP6 point and foot reflexology on severity of labor pain and duration in the first stage of labor

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion Criteria: primigravid and second birth multigravid women; Iranian race; 18-35 years old; at least an elementary school education; singleton pregnancy; live fetus with cephalic presentation; women in the start of active phase of labor; the presence of regular uterine contractions (three contractions in 10 minutes); the gestational age of 37 to 42 weeks (the first day of the last menstrual period (LMP) or ultrasound under 12 weeks); no history of infertility indication Caesarean section; to having a intact amniotic sac or to not past rupture of membranes for more than 12 hours; low risk pregnancy (absence of bleeding in the third trimester; placenta previa; abruption; intrautrine growth restriction) absence of the risk of chronic diseases such as: heart disease, pulmonary, hypertension, diabetes, according to the patient file; not suffering from skin diseases such as: eczema, skin infections and wart in legs; lack of any problems that may lead to the mother's inability to communicate (deafness, blindness); no history of acupressure and reflexology in the past. Exclusion criteria: the client required a Caesarean delivery for any reason (abnormal fetal heart rate pattern; no breakthrough bleeding pregnancy; arrest of labor) mother's unwillingness to continue doing acupressure and or foot reflexology.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization performs by the permutation blocking method.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of the International Branch of Shahid Beheshti University of Medical Sciences and H
Street address
No19, Shahid Abbasspour Street, Valiasr Street,Tehran
City
Tehran
Postal code
14155-3693
Approval date
2014-05-03, 1393/02/13
Ethics committee reference number
116/346

2

Ethics committee
Name of ethics committee
Ethics committee of the Iran University of Medical Sciences and Heath Services
Street address
Hemmat freeway (beside Milad Tower), Tehran
City
Tehran
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
1680/105/92/د

Health conditions studied

1

Description of health condition studied
delivery
ICD-10 code
O80-O84
ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
intensity of pain
Timepoint
Befor 4-5 and 7-8 cm cervical dilatation and 30 minutes after mentioned dilatation
Method of measurement
Visual Analogue Scale

2

Description
Duration of first stage of labor.
Timepoint
From the beginning of 4 cm until 10 cm cervical dilatation.
Method of measurement
Watch ecueped seconds counter.

Secondary outcomes

1

Description
Duration of second stage of labor
Timepoint
From 10 cm dilatation cervix to full expose of fetus
Method of measurement
Swiss Swatch watch

2

Description
Duration of third stage of labor
Timepoint
From full expose of fetus to full expose of placenta
Method of measurement
Swiss Swatch watch

3

Description
First and fifth minutes of apgar.
Timepoint
One and five minutes after birth.
Method of measurement
Standard Apgar Index.

4

Description
Method of delivery
Timepoint
After delivery
Method of measurement
Observation

5

Description
Satisfactory of method of relief labor pain.
Timepoint
After delivery
Method of measurement
Questioner

6

Description
Amount of pain relief
Timepoint
After delivery
Method of measurement
Questioner

7

Description
Tendency to use of pain relief method again
Timepoint
After delivery
Method of measurement
Questioner

Intervention groups

1

Description
Acupressure group: in this group, the SP6 point (where is located in the four fingers above the medial malleouse at the posterior tibia) will be under pressure in two 30-minutes stages from 4 to 5 and 7 to 8 cm dilatation (every two minutes and then rest for one minute until the end of each thirty minutes) by the researcher.
Category
Treatment - Other

2

Description
Reflexology group: in this group uterine zone (located under the medial malleolus foot) and the solar plexus (in the superior and middle border line in the sole) will be under pressure in two 30-minutes stages from the start of 4 to 5 and 7 to 8 cm dilatation (every two minutes and then rest for one minute until the end of each thirty minutes) by the researcher.
Category
Treatment - Other

3

Description
Routine care group: in this group routine care will be done for samples. Also this group received a placebo point touch (dorsal region of foot along with third and fourth finger which is not any pathway meridians).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar Abadi Hospital
Full name of responsible person
Sedigheh Amir Ali Akbari
Street address
Molavi Street, Tehran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of the international branch of Shahid Beheshti University of Medical Sc
Full name of responsible person

Mrs Amir Ali Akbari

Street address

No19, Shahid Abbasspour Street, Valiasr Street, Tehran.

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 of the international branch of Shahid Beheshti University of Medical Sc

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

Obstetrics department of Shahid Beheshti

Full name of responsible person

Mr Amir Ali Akbari

Position

MSc of Midwifery/ lecturer

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Medical Sciences and Health University

Full name of responsible person

Mrs Amir Ali Akbari

Position

Msc

Other areas of specialty/work

Street address

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Email

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Web page address

Person responsible for updating data

Contact

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