

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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 an 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; intrauterine 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 acupuncture 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 acupuncture 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 Abbaspour 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 Health 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

1680/105/92/3

## 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

Before 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 equipped 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 malleolus 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 Abbaspour 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**

**Street address**

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asa\_akbari@yahoo.com

**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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**City**

Tehran

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**Phone**

+98 21 8820 2512

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asa\_akbari@yahoo.com

**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*