

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effectiveness of acupuncture for the initiation of labor at term pregnancy

#### Protocol summary

##### Summary

Background: Prolonged pregnancy associates with increased fetal and maternal complications. The necessity of fetal wellbeing testing during these pregnancies increases the costs. The need for induction of labor increases the rate of cesarean section. Acupuncture stimulates the nervous system by stimulating the parasympathetic system and increasing secretion of oxytocin from the central system, and can cause increased uterine contractility and the onset of labor. Using a safe and low cost method for initiation of labor in term pregnancy can reduce fetal and maternal complications, reduce family stress and may also reduce health care costs. Methods: This randomized double blind clinical trial is done in Shohada hospital. Inclusion criteria are singleton pregnancy , GA>38 weeks , no contraindication of vaginal delivery . Acupuncture is done for case group and sham acupuncture for control group. Routine prenatal care is done for two groups .If labor does not initiate until 42 weeks, induction with oxytocin is started. The time of labor onset , the need to induction of labor, vaginal delivery and cesarean section rate, fetal and maternal complications , Apgar score and patient satisfaction are compared between the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111218151N1**  
Registration date: **2011-12-26, 1390/10/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-12-26, 1390/10/05

##### Registrant information

**Name**

Ladan Ajori

##### Name of organization / entity

Shahid beheshti university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 1694

##### Email address

ajori@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti university of medical sciences

##### Expected recruitment start date

2011-02-25, 1389/12/06

##### Expected recruitment end date

2012-01-26, 1390/11/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of acupuncture for the initiation of labor at term pregnancy

##### Public title

Effectiveness of acupuncture for the initiation of labor at term pregnancy

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: GA>38 w; singleton pregnancy; cephalic presentation; cervical dilatation < 3 cm; intact membrane; no history of cesarean section; no contraindication of vaginal delivery; no skin lesion on acupuncture space; no psychiatric disorders; no indication for emergency delivery; patient inform consent. Exclusion criteria: patient who wants delivery

before 42 w.

### Age

From **15 years** old to **45 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti university of medical sciences

##### Street address

Shahid Beheshti Blv. Yaman street, Chamran highway

##### City

Tehran

##### Postal code

#### Approval date

2011-02-20, 1389/12/01

#### Ethics committee reference number

89-01-136-7307

## Health conditions studied

### 1

#### Description of health condition studied

Initiation of labor

#### ICD-10 code

O35.9

#### ICD-10 code description

Maternal care for (suspected) fetal abnormality and damage, unspecified

## Primary outcomes

### 1

#### Description

Initiation of labor

### Timepoint

The time between Acupuncture and initiation of labor

### Method of measurement

Good contraction of uterus - Cervical dilatation

## Secondary outcomes

### 1

#### Description

Neonatal Apgar

#### Timepoint

at last of study

#### Method of measurement

Apgar score

### 2

#### Description

Fetal complications

#### Timepoint

at last of study

#### Method of measurement

History, physical exam

### 3

#### Description

cesarean

#### Timepoint

at last of study

#### Method of measurement

hospital documents

### 4

#### Description

Maternal complications

#### Timepoint

at last of study

#### Method of measurement

History, physical exam

### 5

#### Description

Induction

#### Timepoint

at last of study

#### Method of measurement

hospital documents

## Intervention groups

### 1

#### Description

Acupuncture (case group)

#### Category

Treatment - Other

2

**Description**

Sham Acupuncture ( control group)

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shohada Hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti university of medical sciences

**Full name of responsible person**

Seyed Jalaledin Khoshnevis

**Street address**

Shohada Hospital - Tajrish square

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Bheshti university of medical sciences

**Full name of responsible person**

Leila Nazari

**Position**

Gynecologist

**Other areas of specialty/work**

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**Web page address**

**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*