

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of the Effect of Nipple Stimulation with Acupressure Point 6 Spleen in the Prevention of Early Pregnancy in Primiparous Women

#### Protocol summary

##### Study aim

Comparison of the effect of nipple stimulation with acupressure spatial point 6 in prevention of postpartum pregnancy

##### Design

The clinical trial has three groups (control, intervention number 1 and 2), randomized

##### Settings and conduct

This study was started at Martyrdom Moghini Sabzevar Hospital in randomly assigned samples at 39 weeks of gestational age.

##### Participants/Inclusion and exclusion criteria

Entry criteria: having a gestational age of 39 to 40 weeks, having a maximum of one delivery, not having a history of cesarean section. Exit criteria: Withdrawal of cooperation, the use of traditional or chemical drugs for induction of labor

##### Intervention groups

The intervention group 1 is recommended to do 3 times every 10 minutes each day until the onset of uterine contractions is triggered by hand. Stimulate each breasts frequently and around the nipple. In the intervention group, 2 people should be pressurized 3 times a day for 1 minute on one leg and then apply pressure on the opposite leg for about 20-30 minutes. The control group receives routine care.

##### Main outcome variables

Preterm pregnancy prevention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151005024371N2**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **retrospective**

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

##### Registration date

2019-01-06, 1397/10/16

##### Registrant information

###### Name

Mozhdeh Navi Nezhad

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 4423 3808

###### Email address

navinm921@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effect of Nipple Stimulation with Acupressure Point 6 Spleen in the Prevention of Early Pregnancy in Primiparous Women

##### Public title

Comparison of the Effect of Nipple Stimulation with Acupressure Point 6 Spleen in the Prevention of Early Pregnancy

##### Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having a gestational age of 39 to 40 weeks Having a maximum of one delivery Singleton pregnancy and Cephalic display Having a low grade score of 4 at the beginning of the study Not having fetal abnormalities in ultrasounds during pregnancy Natural amniotic fluid in ultrasound Not having cesarean history Lack of fast delivery Women with 18to 35 years old

### Exclusion criteria:

Disclaimer of cooperation Use of traditional or chemical drugs to induce labor Failure to perform recommended interventions completely over 1 day

## 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: **177**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The samples were randomly assigned to randomly blocks (Block Randomization) into three groups of 59, called control groups (routine care center), intervention 1 (nipple stimulation) and intervention 2 (spinal cord pressure) Get it.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Sabzevar University Of Medical Sciences

##### Street address

Kashfi Street

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613883778

#### Approval date

2018-09-17, 1397/06/26

## Ethics committee reference number

IR.MEDSAB.REC. 1397.033

## Health conditions studied

### 1

#### Description of health condition studied

Prolonged pregnancy

#### ICD-10 code

O47.9

#### ICD-10 code description

False labour, unspecified

## Primary outcomes

### 1

#### Description

Percentage of people who have an early pregnancy

#### Timepoint

From 39 to 41 weeks pregnant

#### Method of measurement

With a vaginal examination to examine the opening and softness of the cervix

## Secondary outcomes

### 1

#### Description

Progress of labour

#### Timepoint

In active phase per 1 hour

#### Method of measurement

Partograph

## Intervention groups

### 1

#### Description

Control group: The observation of 59 mothers from the 39th week of gestation based on the first day of the last menstrual period or the first three months of the first sonoon and the daily control of the fetal heart sounds until the onset of labor pain and admission to the maternity ward for delivery

#### Category

Prevention

### 2

#### Description

Intervention group 1: 59 women who are recommended from 39 weeks of gestation are recommended 3 times daily for 10 minutes until the onset of uterine contractions. Stimulate each breasts frequently and around the nipple.

#### Category

Prevention

### 3

#### Description

Intervention group 2: Apply 3 times daily for 1 minute on one leg and then apply pressure on the opposite leg for about 30 to 20 minutes later.

#### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Mobini hospital

###### Full name of responsible person

Mitra Eftekhar Yazdi

###### Street address

Kashfi Street

###### City

Sabzevar

###### Province

Razavi Khorasan

###### Postal code

9613883778

###### Phone

+98 51 4423 8100

###### Email

navinm921@mums.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Sabzevar University of Medical Sciences

###### Full name of responsible person

Fereshteh Ghorat

###### Street address

Asad abadi Street

###### City

Sabzevar

###### Province

Razavi Khorasan

###### Postal code

9613883778

###### Phone

+98 51 4423 8100

###### Email

drghorat@gmail.com

###### Grant name

###### Grant code / Reference number

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

Yes

###### Title of funding source

Sabzevar University of Medical Sciences

###### Proportion provided by this source

100

###### Public or private sector

Public

###### Domestic or foreign origin

Domestic

###### Category of foreign source of funding

empty

###### Country of origin

###### Type of organization providing the funding

Academic

### Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mozhdeh Navi Nezhad

##### Position

Academic instructor

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

Kashfi Street

##### City

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### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mozhdeh Navi Nezhad

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Academic instructor

##### Latest degree

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## Person responsible for updating data

### Contact

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Sabzevar University of Medical Sciences

**Full name of responsible person**

Mozhdeh Navi Nezhad

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**Phone**

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**Email**

navinm921@mums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All participants' data will be available to applicants

**When the data will become available and for how long**

Within 6 months after the publication of the article

**To whom data/document is available**

Professors and academic researchers

**Under which criteria data/document could be used**

Doing an analysis on delivered data is not allowed

**From where data/document is obtainable**

The author is responsible and by request via email

**What processes are involved for a request to access data/document**

After requesting by email, within 10 days, the requested information will be provided to the applicant

**Comments**