

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of foot reflexology on reduction post partum after pain

#### Protocol summary

##### Study aim

The results of this study may lend support to relieving postpartum pain by using reflexology as a replacement or supplement of analgesics.

##### Design

The participants of this study that is a clinical treatment, will be 68 eligible postpartum women (34 in the reflexology group and 34 in the control group) referring to the Department of Obstetrics of Razi Hospital of Ahvaz. Sampling will be done using randomized blocks of four

##### Settings and conduct

The study will be conducted at Razi Hospital of Ahvaz. Sixty-eight women whose afterpains score is moderate and severe (3.1-10) will be selected and divided into two groups of control and intervention using randomized blocks of four. The intervention group will receive reflexology for both feet for 20 min on the intended points while the control group will receive only the routine care.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Spontaneous vaginal delivery 2. Singleton pregnancy 3. Cephalic presentation 4. Mother's complaint of moderate or severe postpartum pain (a pain score of 3.1 or above based on Visual Analogue Scale) 5. Age between 18-35 6. Second to fourth parity  
Exit criteria 1. Hard and prolonged delivery 2. Mother's substance abuse 3. Postpartum hemorrhage 4. Underlying illnesses (blood pressure, diabetes, kidney problem, etc.) 5. Any problem with the soles such as corns, burns, cuts, fungal infection, varicose veins, warts or any numbness in the foot 6. Still births

##### Intervention groups

In the intervention group, 34 eligible women will receive reflexology at certain points in their feet. The control group will receive only the routine care.

##### Main outcome variables

Postpartum afterpains, the severity of afterpains, duration of afterpains

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171208037792N1**

Registration date: **2018-07-14, 1397/04/23**

Registration timing: **retrospective**

Last update: **2018-07-14, 1397/04/23**

Update count: **0**

##### Registration date

2018-07-14, 1397/04/23

##### Registrant information

##### Name

galiya bakhtiyari niya

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3222 3747

##### Email address

galiyabakhtiyari21@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-04, 1397/01/15

##### Expected recruitment end date

2018-06-05, 1397/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of foot reflexology on reduction post partum

after pain

### Public title

The effect of foot reflexology on reduction post partum after pain

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Natural childbirth Being semicolon Single baby Cephalic display Approximate weight 2500-4000 Mother's complains of moderate or severe labor pain Age 18-35 Second to fourth childbirth Body mass index between 18.5-29.9

#### Exclusion criteria:

Hard and prolonged delivery Mother drug addiction History of postpartum hemorrhage Background of the underlying disease History of lesion in the leg Stillbirth Fetal Dead Intense stress

### Age

From **18 years** old to **35 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

- Care provider

### Sample size

Target sample size: **68**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Sampling of the subjects and their grouping into control and intervention groups will be done using randomized blocks of four.

### 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

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences and Health Services

##### Street address

Ahvaz Jundishapur University of Medical Sciences and Health Services ,Golestan BLV, Ahvaz

##### City

Ahvaz

### Province

Khuzestan

### Postal code

61357-15794

### Approval date

2018-04-04, 1397/01/15

### Ethics committee reference number

IR.AJUMS.REK.1396.494

## Health conditions studied

### 1

#### Description of health condition studied

Post partuum After pain

#### ICD-10 code

Z39

#### ICD-10 code description

Encounter for maternal postpartum care and examination

## Primary outcomes

### 1

#### Description

Post Partum After Pain (Pain score between middle and high)

#### Timepoint

Determining the severity of pain by Visual Analogue Scale(VAS) before and after the intervention, immediately after intervention,at minutes 30, 60, 120, and 6 hours after the intervention, and the duration of the pain in the interval between the onset of the intervention and the mild pain.

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

post partum afterpain

#### Timepoint

Determining the severity of pain by Visual Analogue Scale(VAS) before and after the intervention, immediately after intervention,at minutes 30, 60, 120, and 6 hours after the intervention, and the duration of the pain in the interval between the onset of the intervention and the mild pain

#### Method of measurement

Visual Analogue Scale

## Intervention groups

### 1

#### Description

Intervention group: Reflexologylasting for 10 minutes at the points of interest on each leg. Pituitary, (behind the

toes) Solar plexus (found by drawing an imaginary line from the third toe down to just below the ball of the foot) the inner arch of the foot and the uterus (the area between the ankles in the leg and the heel)

**Category**

Treatment - Other

**2****Description**

group: Massage of other parts of the foot or routine care

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Department of Obstetrics and Gynecology, Ahvaz Razi Hospital

**Full name of responsible person**

Galiya Bakhtiari Nia

**Street address**

Ahvaz Amaniye Department of Obstetrics and Gynecology, Razi Hospital

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**Web page address**

[http://fa.irct.ir/user/trial/28558/update/recruitment\\_center](http://fa.irct.ir/user/trial/28558/update/recruitment_center)

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Galiya Bakhtiari Nia

**Street address**

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**Web page address**

<http://fa.irct.ir/user/trial/28558/update/sponsor>

**Grant name****Grant code / Reference number**

دانشگاه علوم پزشکی اهواز

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

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Other

**Person responsible for general inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

گالیا بختیاری نیا

**Position**

ماما

**Latest degree**

Bachelor

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Bakhtiari Galiya Nia

**Position**

Midwife

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Bakhtiari Galiya Nia

**Position**

Midwife

**Latest degree**

Bachelor

### **Other areas of specialty/work**

Midwifery

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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

### **Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

### **Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

### **Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

### **Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

### **Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

### **Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available