

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### A Comparison Study of the Effect of foot reflexology with and without violet oil on fatigue, pain after cesarean section in patients

#### Protocol summary

Fatigue, pain

##### Study aim

Determining the comparison of the effect of plantar reflexology with and without violet oil on fatigue and pain after cesarean section in patients referred to Tohid Jam Hospital in Bushehr, 2021

##### Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 126 patients. Randomizer software was used for randomization.

##### Settings and conduct

From the patients referred to Tohid Jam hospital in Shiraz, based on the inclusion criteria, 126 samples were selected by convenience sampling method and randomly assigned to a control group and two intervention groups using Randomizer web-based software. One-way blinding and intervention and control groups are not aware of the type of intervention. Sealed consecutive matte envelopes were used to conceal the allocation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Being 18-45 years old; Literacy; Perform cesarean section with spinal anesthesia; Complete pregnancy and healthy baby and high Apgar score of the first minute; No allergies to used oils; No skin problems in the massage area; Do not use narcotic sedatives in the last eight hours; Do not be under general anesthesia. Exclusion criteria: Having severe postoperative complications such as excessive bleeding, infection, eclampsia, hospitalization in intensive care units; Reluctance to continue cooperation during stages 2 and 3.

##### Intervention groups

Group 1: In the first group, the reflexology intervention of the sole of the foot will be performed with violet oil. Second group: In the second group, the reflexology intervention of the sole of the foot will be performed without violet oil. The third group: in this group are cesarean section patients who are not subjected to any intervention.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211204053272N1**

Registration date: **2022-01-01, 1400/10/11**

Registration timing: **prospective**

Last update: **2022-01-01, 1400/10/11**

Update count: **0**

##### Registration date

2022-01-01, 1400/10/11

##### Registrant information

##### Name

Esmat Mardani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4254

##### Email address

esmatmardani6609@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-03-21, 1401/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A Comparison Study of the Effect of foot reflexology with and without violet oil on fatigue, pain after cesarean section in patients

### Public title

The effect of plantar reflexology on fatigue and pain after cesarean section

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Being 18-45 years old Literacy Perform cesarean section with spinal anesthesia Complete pregnancy and healthy baby and high Apgar score of the first minute No allergies to used oils No skin problems in the massage area Do not use narcotic sedatives in the last eight hours Do not be under general anesthesia

#### Exclusion criteria:

Having severe postoperative complications such as excessive bleeding, infection, eclampsia, hospitalization in intensive care units Reluctance to cooperation during stages 2 and 3

### Age

From **18 years** old to **45 years** old

### Gender

Female

### Phase

1-2

### Groups that have been masked

- Participant

### Sample size

Target sample size: **126**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization is done in a simple and individual way using Randomizer random allocation software. Individuals are listed according to the national code and then divided into groups 1 (reflexology with violet oil), group 2 (reflexology without oil) and group 3 (control) using random allocation software.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Only the researcher knows which patient is in the control group and which is receiving reflexology with oil or without oil. Patients are not aware of their groups.

### Placebo

Not used

### Assignment

Parallel

### Other design features

### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences, Shiraz,Iran

##### City

Shiraz

##### Province

Fars

##### Postal code

۷۱۳۳۶ - ۷۱۳۴۸

#### Approval date

2021-09-25, 1400/07/03

#### Ethics committee reference number

IR.SUMS.NUMIMG.REC.1400.036

## Health conditions studied

### 1

#### Description of health condition studied

Cesarean section

#### ICD-10 code

O75.82

#### ICD-10 code description

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

## Primary outcomes

### 1

#### Description

Fatigue

#### Timepoint

Before studying and one hour after studying

#### Method of measurement

Multidimensional Fatigue Inventory scale

### 2

#### Description

Pain

#### Timepoint

Before studying and one hour after studying

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group 1: The reflexology intervention of the sole of the foot will be performed with violet oil. After washing the patients's soles and drying them while lying down, the researcher will perform a foot reflexology with 3-5 cc of violet oil for 40 minutes (20 minutes for each foot). The number of intervention sessions will be four times a week for two consecutive days (twice a day at intervals of 6-8 hours). The intervention begins after the patient has RBR (8 to 10 hours after cesarean section) and subsequent reflexology sessions will be performed at approximately a fixed time interval. Diclofenac suppositories are given at each stage of the study if severe pain and analgesia are needed.

### Category

Treatment - Drugs

## 2

### Description

Intervention group 2: The foot reflexology intervention will be performed without violet oil. After washing the patients's soles and drying them while lying down, the researcher will perform foot reflexology without violet oil for 40 minutes (20 minutes for each foot). The number of intervention sessions will be four times a week for two consecutive days (twice a day at intervals of 6-8 hours). The intervention begins after the patient has RBR (8 to 10 hours after cesarean section) and subsequent reflexology sessions will be performed at approximately a fixed time interval. Diclofenac suppositories are given at each stage of the study if severe pain and analgesia are needed.

### Category

Treatment - Other

## 3

### Description

Control group: In this group are cesarean section patients who are not subjected to any intervention. Patients in this group are only monitored. Diclofenac suppositories are given at each stage of the study if severe pain and analgesia are needed.

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Tohid Jam Hospital in Bushehr

#### Full name of responsible person

Esmat Mardani

#### Street address

Jam city, Tohid town, Tohid Jam hospital, Bushehr, Iran

#### City

Bushehr

#### Province

Boushehr

#### Postal code

7558174946

#### Phone

+98 77 3762 3003

#### Email

Esmatmardani6609@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr. Fatemeh Ghavi

#### Street address

Namazi Square "Namazi Hospital" Fatemeh School of Nursing and Midwifery, Shiraz, Iran

#### City

Shiraz

#### Province

Fars

#### Postal code

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#### Phone

+98 71 3647 4254

#### Email

ghavi.fatemeh@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz University of Medical Sciences

#### Proportion provided by this source

65

#### 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

Shiraz University of Medical Sciences

#### Full name of responsible person

Fatemeh Ghavi

#### Position

Instructor of Midwifery

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Midwifery  
**Street address**  
Namazi Square "Namazi Hospital" Fatemeh School of  
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**City**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for updating data

### Contact

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Shiraz University of Medical Sciences  
**Full name of responsible person**  
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**Email**  
ghavi.fatemeh@yahoo.com

## 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

Not applicable

### Data Dictionary

Not applicable

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

Article

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

2022

### To whom data/document is available

Researchers working in academic and scientific institutions

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

1- Reference in articles and dissertations 2- Having a code of ethics in your studies 3- Valid academic emails

### From where data/document is obtainable

Esmat Mardani Hazrat Fatemeh Shiraz School of Nursing and Midwifery Esmatmardani6609@gmail.com 00989173894438

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

Communication via valid email

### Comments