Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

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

Protocol summary

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
Fatigue, pain

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 Comparision 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
۱۴۳۳۶ - 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

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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

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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
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Namazi Square "Namazi Hospital" Fatemeh School of Nursing and Midwifery, Shiraz, Iran
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Person responsible for updating data

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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