

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The examining of the effect of foot massage with orange essence on grade pain and anxiety women under cesarean section.

Protocol summary

Study aim

Definition of effect of foot massage with orange essence on grade pain and anxiety women under cesarean section.

Design

The study population include women under cesarean section who are referred to bahar hospital of Shahrood. Sample size is 80. Sampling will be carried out using sequential sampling method and assignment of research units will be performed to intervention and control groups by blocking method. pain and anxiety will be measured using the questionnaires. In intervention group, foot massage with orange essence will intervene. Then the variables are measured immediately after intervention and 60 minuet after the intervention, in both groups.

Settings and conduct

bahar hospital of Shahrood, The person collecting information before and after the intervention and analyzer are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nulliparous mothers with cesarean section; No Medical condition in mother; mothers with no tissue damage on their feet; using Spinal analgesia for cesarean section; have Gcs 15. Exclusion criteria: mothers who have serious health disorder. mothers who have tissue damage on their feet.

Intervention groups

In the intervention group, foot massage with orange essence and the second group is also a control group and foot massage without orange essence will be performed in this group. Before the intervention (4 hour after receive initial dose sedative prevalent bakhsh), the information are collected using demographic characteristics form and vas visual criterion and spielberger anxiety questionnaires. in intervention group massage with 10 till 15 cc orange essence 1.5 percent will be performed. Immediately after the intervention and 60 minuet after the intervention, pain and anxiety will be

measured.

Main outcome variables

pain, anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181226042137N1**

Registration date: **2019-04-27, 1398/02/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

Registration date

2019-04-27, 1398/02/07

Registrant information

Name

Nastaran Norozi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3238 0469

Email address

norozi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The examining of the effect of foot massage with orange essence on grade pain and anxiety women under cesarean section.

Public title
The examining of the effect of foot massage with orange essence on grade pain and anxiety women under cesarean section.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Inclusion criteria: Nulliparous mothers with cesarean section; mothers with the age of 20-45 years old; mothers should be literate; No Medical condition in mother (cardiac, respiratory, hepatic or neurologic); mothers with no tissue damage on their feet; using Spinal analgesia for caesarean section; have Gcs 15.
Exclusion criteria:
 mothers who have serious health disorder. mothers who have a tissue damage on their feet.

Age
From **20 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
Randomize by quadrilateral blocking. The randomization sequence will be carried out secretly. That is, there are 20 envelopes packed in each A and B code. After obtaining informed consent and ascertaining that the person is participating in the study, the researcher will take the desired envelope in accordance with the order and will proceed according to the group recorded in the envelope.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Secondary trial Id

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrood University of Medical Sciences

Street address

Tehran street, 7 tir Square.

City

shahrood

Province

Semnan

Postal code

36147 73947

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.SHMU.REC.1397.194

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Before intervention; Instantly After intervention and 60 minute After intervention.

Method of measurement

VAS visual criterion

2

Description

anxiety

Timepoint

Before intervention; Instantly After intervention and 60 minute After intervention.

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group foot massage will be performed with 10 till 15 cc orange essence 1.5 percent with basic techniques from region ankle till toes each 5 minuet and altogether 10 minuet per researcher educated .

Category

Behavior

2

Description

Control group: in this group foot massage will be performed without orange essence with basic techniques from region ankle till toes each 5 minuet and altogether 10 minuet per researcher educated .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital in Shahrood

Full name of responsible person

Nastaran Norouzi

Street address

Tehran Street

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Semnan

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3614773947

Phone

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Email

nastarannorouzi96@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad hasan Emamian

Street address

Tehran Street

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emamian@shmu.ac.ir

Grant name

Vice chancellor of Research and technology of Shahroud University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Nastaran Norouzi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Surgical Technologist

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Fatemeh Mobaraki

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Shahrood University of Medical Sciences
Full name of responsible person
Nastaran Norouzi
Position
Student
Latest degree
Bachelor
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Surgical Technologist
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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