

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of Reflexology and relaxation of Benson on pain, physiological symptoms, lactation and weight of newborn in women undergoing cesarean section, admitted to Persian Gulf Shohada Hospital of Bushehr in 2018

Protocol summary

Study aim

Determining the effect of reflexology and Benson's relaxation on pain, physiological symptoms, lactation and weight of newborn in women undergoing c/s

Design

This project will be a clinical trial, without blindness. Random allocation will perform with block randomization. 135 contributors will be randomly assigned to 3 groups (45 in each group). In reflexology and Benson's relaxation groups, intervention will be performed two hours after surgery and again six hours later and the variables will be measured

Settings and conduct

The field of this research will be the gynecology ward of the Persian Gulf Mortyrs Hospital, Bushehr. In the Benson reflexology and relaxation group, the intervention will be performed once every two hours after surgery and again 6 hours later, and the variables will be measured immediately, 30 and 60 minutes after the intervention. In the control group, routine care will be performed. The variables will be measured in parallel with the two intervention groups.

Participants/Inclusion and exclusion criteria

Include: Elective caesarean section; spinal anesthesia; Age 18-35; First or second Pregnancy. Not include: rupture of membrane; mental or physical disorder; Pain score below 3 at the beginning of intervention; The hospitalization of newborns in the NICU; Any kind of disorder that causes the problem of infant feeding; Any problem with the mother that prevents lactation

Intervention groups

Two intervention groups including Benson reflexology and relaxation group and a control group. The intervention will be performed two and six hours after the operation, and the variables will be measured immediately, 30 and 60 minutes after the intervention. In

the control group, routine care will be taken and the variables will be measured in parallel with the two intervention groups, .

Main outcome variables

Pain; Physiological index; lactation; Weight of infant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190122042453N1**

Registration date: **2019-04-05, 1398/01/16**

Registration timing: **prospective**

Last update: **2019-04-05, 1398/01/16**

Update count: **0**

Registration date

2019-04-05, 1398/01/16

Registrant information

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Razieh Bagherzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Reflexology and relaxation of Benson on pain, physiological symptoms, lactation and weight of newborn in women undergoing cesarean section, admitted to Persian Gulf Shohada Hospital of Bushehr in 2018

Public title

Investigating the effect of Reflexology and relaxation of Benson on pain, physiological symptoms, lactation and weight of newborn in women undergoing cesarean section

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Having the consent to participate in the study Not an emergency Caesarean section Spinal anesthetics Gestational age at least 37 weeks and maximum 42 weeks according to the exact date of the first day of the last menstruation or first trimester ultrasound At least reading and writing skills Age range 18-35 Being aware of time and place No drug addiction, sedation, alcohol, etc. According to the self-declaration of the research unit Absence of any mental disorder due to the self-explanation of a research unit or a physical impairment affecting the sensation of the leg such as diabetes No history of using foot massage or relaxing Benson First or Second Pregnancy Having single-strike pregnancy and low risk Lack of simultaneous surgery such as hysterectomy and tuberculosis Having a healthy leg in the foot, especially The sole of the foot, (no cuts, burns, fungal infection, varicose veins, warts, corns and any kind of anesthetics in the feet, lack of sensitivity to touch or massage Failure to report congenital anomalies in patient's ultrasound The absence of pregnancy complications such as blood pressure Do not tear a sack of water

Exclusion criteria:

Severe complications after surgery or during hospitalization such as severe bleeding, edema, acute infection and non-ablation of the uterus after surgery Incident in the operating room The need for more care in the intensive care unit Perform non-transverse cutting on the uterus or abdomen according to the description of the patient's operation Pain score below 3 at the time of the decision to intervene Cancellation of the continuation of the research Having an unpleasant participant's sensation of touching the foot in the Foot Reflexology massage group The hospitalization of newborns undergoing cesarean section in the NICU department There is any kind of disorder that causes the problem of infant feeding, such as Cleft palate and Lip are not detected, Galactosoma The occurrence of any problem in

the mother that prevents lactation, such as unpleasant events, breast abscess, etc. (in this case, only the babies of these mothers will not be included in the study)

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: 135

Randomization (investigator's opinion)

Randomized

Randomization description

According to block the research sample will be placed into one of the three groups of foot reflexology, Benson relaxation, or control group. The number of required blocks will be selected randomly. For blocking, 22 blocks of 6 blocks and a triple block will be used. Block size 6 and 3 will be used. In the first step, blocks size 6 are prepared using A (Reflexology), B (Benson relaxation intervention) and C (Control group), which will have 90 different modes. Of the blocks, 22 will be randomly selected. By selecting each six blocks, each one will be placed in one of three groups according to the order of the letters of the letters: each block will receive two chances for each group. Block size 3 will also be provided (6 modes) and one block will be randomly selected.

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 Bushehr University of Medical Sciences

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Moallem St., Kuy-e-Bandar

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Postal code

7514633341

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Physiological Index

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Neonate weight

ICD-10 code

ICD-10 code description

4

Description of health condition studied

Breast feeding (number of times and mean times of breast feeding during 18 hours after c/s)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, immediately after intervention, 30 and 60 second after intervention

Method of measurement

Visual scale of pain,

2

Description

Physiological symptoms (pulse, BP and O2 saturation)

Timepoint

Before intervention, immediately after intervention, 30 and 60 second after intervention

Method of measurement

Barometer, Pulse oximetre

Secondary outcomes

1

Description

Breast feeding (number and mean of times of breast feeding during first 18 hours after birth)

Timepoint

During 18 hours after c/s. To check the frequency and time of breastfeeding, a checklist is provided; each breastfeeding period and its duration up to 18 hours after cesarean section will be recorded by a researcher or nurse responsible for the baby.

Method of measurement

Observation and statement by researcher and responsible nurse

2

Description

Baby weight

Timepoint

The first and the tenth day after cesarean section

Method of measurement

Baby weighing scale

Intervention groups

1

Description

Intervention group: Benson's relaxation will be performed two hours after c/s and 6 hour after first episode of intervention. The duration of intervention will be 20 minutes each time. Then, the variables (physiological indices, pain) will be immediately measured 30 and 60 minutes after each intervention. The frequency of breastfeeding will be measured in 18 hours after the operation. On the day of surgery and ten days after the operation, the baby weight will be measured.

Category

Treatment - Other

2

Description

Control group: In this group no intervention will perform by researcher. Routine care will be provided by department personnel. The variables required for research will be measured parallel with two intervention groups.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Persian Gulf Shohada Hospital

Full name of responsible person

Razieh Bagherzadeh

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Sponsors / Funding sources

1

Sponsor

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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

Boushehr 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
Boushehr University of Medical Sciences
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Position
Assistant Professor
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Person responsible for updating data

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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