Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 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

Name

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 scienece
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
Street address
Moallem St., Kuy-e-Bandar
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Bushehr
Province
Boushehr
Postal code
7514633341
Approval date
2019-03-11, 1397/12/20
Ethics committee reference number

IR.BPUMS.REC.1397.142

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 oximetere

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

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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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Razieh Bagherzadeh
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Reproductive Health
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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