Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Clinical trial of The effect of foot reflexology on anxiety and physiological parameters primiparous before elective cesarean in womens department at emam ali hospital

Protocol summary

Summary

This study is a randomized single-blind clinical trial performed with the aim of evaluating the effect of foot reflexology on anxiety and primiparous physiological parameters before elective cesarean in gynecology department at Emam ali Hospital. The study population included pregnant women referred to Emam ali Hospital in Zahedan city. Ninety pregnant women eligible for the study were selected by purposive sampling and distributed in three groups (reflexology group, placebo and control) according to draw by random assignment in units. On the first day of the study, the extent of anxiety was determined by Spielberger questionnaire and after recording the patient's vital signs, the foot was stained with baby oil and the massage was done for 30 minutes in 3 steps in reflexology group. In the placebo group, reflex points on the soles of the feet (except for the points associated with anxiety) were massaged with less pressure than reflexology group for 30 minutes. In the control group, no interventionwas made and only vital signs and tools were recorded according to research process of registration. The physiological and anxiety levels in all three groups were again measured immediately after the intervention. In addition, this study was conducted on women one hour before transferring the patient to operation room for cesarean section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122723370N3**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Maryam Navaee

Name of organization / entity

Nursing and Midwifery Faculty

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of The effect of foot reflexology on anxiety and physiological parameters primiparous before elective cesarean in womens department at emam ali hospital

Public title

The effect of foot reflexology on anxiety and physiological parameters primiparous before cesarean

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age 18-35 years old; having healthy foot; lack of sensitivity to touch or massage; not having reflexology history; not being addict (sedative, alcohol and...); orientation to time and place; primiparous women referred to womens department for elective cesarean; obtain a minimum score of 20 from Spielberger anxiety inventory. Exclusion criteria: not willing to participate in research; severe complication such as sever blood presure.
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: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research, Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences, Khalije Fars Boulevard, Zahedan, Iran
City
Zahedan
Postal code
Approval date
2015-11-08, 1394/08/17
Ethics committee reference number
IR.SBMU.EMRC.REC.1394.6985

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Anxiety
Timepoint
Before and immediately after the intervention
Method of measurement
With anxiety inventory Spillberger

2

Description
Physiological Parameters
Timepoint
Before and immediately after the intervention
Method of measurement
Barometer, Thermometer and Hand

Secondary outcomes

1

Description
Fear
Timepoint
Before and immediately after the intervention
Method of measurement
Childbirth Attitude Questionnaire

Intervention groups

1

Description
On the first day of the study, the extent of anxiety was determined by Spielberger questionnaire and after recording the patient's vital signs, the foot was stained with baby oil and the massage was done for 30 minutes in 3 steps in reflexology group.The physiological and anxiety levels were again measured immediately after the intervention
Category
Prevention

2

Description
In the placebo group, reflex points on the soles of the feet (except for the points associated with anxiety) were massaged with less pressure than reflexology group for 30 minutes.

Category
Prevention

3

Description
In the control group, no interventionwas made and only vital signs and tools were recorded according to research process of registration. The physiological and anxiety levels in all three groups were again measured immediately after the intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali Hospital
Full name of responsible person
Zinat Pharokhfal
Street address
Khalije Fars Boulevard, Zahedan, Iran
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Zahedan University of Medical Sciences
Full name of responsible person
Dr. Mohsen Taheri
Street address
Zahedan University of Medical Sciences, Khhalije fars Square, Zahedan,Iran
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty