

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 intervention was 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

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 4510

Email address

navaee.m@zamuc.ac.ir

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 intervention was 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

Full name of responsible person
Maryam Navaee

Position
Master degree, faculty member

Other areas of specialty/work

Street address
Behdasht Street, Zahedan, Iran

City
Zahedan

Postal code

Phone
+98 54 3344 4510

Fax

Email
helennavaee@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of Nursing and Midwifery

Full name of responsible person
Maryam Navaee

Position
Master degree

Other areas of specialty/work

Street address
Behdasht Street, Zahedan, Iran

City
Zahedan

Postal code

Phone
+98 54 3344 4510

Fax

Email
helennavaee@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Faculty of Nursing and Midwifery

Full name of responsible person
Maryam Navaee

Position
MSc

Other areas of specialty/work

Street address
Behdasht street, Zahedan, Iran

City
Zahedan

Postal code

Phone
+98 54 3344 4510

Fax
Email
helennavaee@gmail.com
Web page address

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