

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the Effect of Hand Reflexology on Postpartum Pain in Multiparous Women: A Randomized Controlled Clinical Trial Study

Protocol summary

Study aim

1-Determining and Comparing the severity of After Pain before the Intervention, Immediately after the Intervention, during 30, 60, and 120 Minutes after the Intervention and 24, 48, and 72 Hours after Delivery in the Verum Reflexology Group 2-Determining and Comparing the Intensity of After Pain before the Intervention, Immediately after the Intervention, during 30, 60, and 120 Minutes after the Intervention and 24, 48, and 72 Hours after Delivery in the Sham Reflexology Group 3- Determining and Comparing the Severity of After Pain at the designated Times, during 30, 60, and 120 Minutes after the designated Times and 24, 48, and 72 Hours after delivery in the Routine Care Group

Design

A clinical trial with a control group, parallel-group, single-strain, randomized, phase II ? on 90 women after childbirth. Excel software is used for randomization.

Settings and conduct

In this study, the research environment will be the postpartum care department of hospital Bent Al-Hoda in Bojnord city and Javadalaimeh in Jajarm city.

Participants/Inclusion and exclusion criteria

log in 1- It should be multipar 2- Natural birth without tools 3- In general, he should not have any lesions or problems in his hands 4- He does not have mental problems and anxiety, he has not used drugs affecting the nervous system Failure to enter 1-Receive less than 2 times real or sham reflexology

Intervention groups

In the real reflexology group, in each hand, first 3 minutes of general massage, then real reflexology is performed Sham reflexology group also performs 3 minutes of general massage on each hand, then Sham reflexology is performed in the form of ineffective pressure. The routine care group receives only routine postpartum care.

Main outcome variables

reducing the intensity of post-partum pain; Reducing the

amount of pharmaceutical painkillers after delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230710058736N1**

Registration date: **2023-10-22, 1402/07/30**

Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**

Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name

Fateme Sahebi mofrad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty Scientific title Investigating the Effect of Hand Reflexology on Postpartum Pain in Multiparous Women: A Randomized Controlled Clinical Trial Study Public title Investigating the Effect of Hand Reflexology on Postpartum pain Purpose Supportive Inclusion/Exclusion criteria Inclusion criteria: The Research Unit is willing to Participate in the Study Be Iranian Be 15-45 Years Old Body Mass Index is 18.5-29.9 Be Multi-par Be Single Do not have a High-Risk Pregnancy (Pre-Eclampsia, Placental Abnormalities Such as Placental Abruption, Placenta Previa and Placenta Accreta, Chorioamnionitis and Diabetes with Insulin) The Presentation of the Fetus is Cephalic Natural Birth without Tools Do not have Abnormal Bleeding after Delivery The Baby's Weight Should be 2500-4000 Grams Wounds, Burns, Fungal Infections, Warts, Varicose veins, Thickening of Skin Layers, often Yellow in Color, Numbness, and in General, do not have any Lesions or Problems in the Hands Don't have Contagious Skin Disease on Hands such as Scabies, Chicken Pox, Jaundice He doesn't have Mental Problems and Anxiety, he doesn't use Drugs that Affect the Nervous System The Mother should not be Prohibited from Breastfeeding The Intensity of the Back Pain should be Mild to Severe According to the Numerical Rating Scale of Pain The Placenta and Membranes have not been Removed by Hand (Uterine Courage). Exclusion criteria: The Research Unit does not want to Continue Participating in the Research Received Additional Treatments to Control Postpartum Bleeding (such as Oxytocin, Methylergonovine, Prostaglandin E1, Prostaglandin f2α, Blood Transfusion, Surgery) Uterine Curettage has been Performed During the Study The Mother is unable to Continue Breastfeeding Receive less than 2 Times Verum or sham reflexology Age From 15 years old to 45 years old Gender Female Phase N/A Groups that have been masked • Participant • Care provider Sample size Target sample size: 90 Randomization (investigator's opinion) Randomized Randomization description It is accessible (simple) and goal-oriented. All patients who meet the conditions for entering the study are examined. Random Allocation of Samples will be done	using Excel Software. Finally, People will be divided into 3 Groups: Verum Intervention (30 people), Sham Intervention (30 people) and Routine Care (30 people). Blinding (investigator's opinion) Single blinded Blinding description The Research Unit will be Randomly assigned to 3 Groups: Verum Intervention, Sham Intervention and Routine Care Using Excel Software. The Verum and Sham Intervention Groups will be Fully Explained about the Objectives of the Research and not only about the Existence of the Routine Care Group, but also about the Fact that they may be Randomly Placed in one of the Two Verum Intervention Groups. The Sham Intervention is Similar to the Verum Intervention in every way, Including the Place, Time, Technique and Frequency of the Intervention, and the only Difference is in the Amount of Pressure Applied and thus Blinding. It is done because they do not know Exactly the Type of Intervention. One of the Limitations of the Research is the Detailed Explanation of the Objectives of the Research to the Routine Care Group. The Explanation to this Group is that the Study will be conducted with the Aim of Investigating the Severity of Postpartum Pain, and it is tried to Separate the Room of the Routine Care Group from the other Two Groups. Also, the Clinical Caregivers (Nurses and Midwives of the Post-Partum Department) and Gynecologists of the Center know about the Objectives of the Research, but they do not know the Type of Intervention Received by each Research Unit, in Fact, they do not know which Intervention each Person received. Placebo Used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Faculty of Pharmacy and Midwifery Nursing, Shahid Beheshti University of Medical Street address Block A, 13th floor, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simai Iran Street, between South Flamak and Zarafshan, Quds Town (West), Tehran. City Tehran Province Tehran Postal code 1985717443
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Approval date

2023-10-11, 1402/07/19

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.118

Health conditions studied**1****Description of health condition studied**

Postpartum uterine pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Postpartum pain

Timepoint

Within 2 hours before the intervention, immediately after the intervention, within 30, 60, and 120 minutes after the intervention and 24, 48, and 72 hours after delivery.

Method of measurement

Numerical rating scale is a tool to measure the intensity of pain, which is in the form of a 10 cm ruler with 11 numbers.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Verum reflexology group in each hand, first, 3 minutes of massage, then the real reflection of the thumb and the researcher reflects the pressure snake in the heart reflection and the solar network and pressure with the Mole technique in the pituitary and uterine reflexion area, the pressure rate in the reflection areas is so high that the research unit does not feel pain and not in the third third of the thumb. The reflection time in each refrigerator area is 2 minutes, and in the past 9 minutes of intervention time for the right hand (the heart reflection area only in the left hand) and 11 minutes of intervention time for the left hand

Category

Treatment - Other

2**Description**

Intervention group: Sham reflexology group in each hand, first, 3 minutes of massage, then the reflection of the shaped by the thumb and the researcher referring, the pressure of the snake in the reflective and distribution of the solar and the solar network, and the high-end system with the Mole technique in the pituitary

and uterine reflexent region, the rate of pressure in reflective areas is so high that it does not create a color in the upper third thumb. The duration of the reflection of the sham in each refrigerator area is 2 minutes, and in the past 9 minutes of intervention time for the right hand (the heart reflection area only in the left hand) and 11 minutes of intervention time for the left hand

Category

Placebo

3**Description**

Control group: The routine care group receives only routine care after delivery

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bent Al-Hoda Hospital

Full name of responsible person

fateme sahebi mofrad

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Western Taleghani St, Zaishgah Crossroads, Honar St, Bent Al Hoda Hospital

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2**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Afshin Zarghi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fateme Sahebi mofrad

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Latest degree

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Other areas of specialty/work

Midwifery

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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