

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of foot reflexology in the fourth stage of labor on after pain and postpartum hemorrhage

Protocol summary

Postpartum hemorrhage;after pain

Study aim

Determine the effect of foot reflexology in the fourth stage of labor on postpartum pain and postpartum hemorrhage

Design

Clinical trials with control group, randomized

Settings and conduct

This study will be carried out on women who have normal delivery to Alamah Behnoui hospital in Gonabadi. After the third stage of labor, the obstetrician, without informing the mother (one blinded), in the intervention group, was given 4 minutes of massage at each leg And then 2 minutes of specific reflexology in each of the uterus, pituitary, solar network is performed in rotational pressure. This operation is also repeated at the second hour after delivery. In the control group, the intervention This will not happen. Blood volume is measured at the first and second hours after delivery and after pain during the first, second, third and fourth hour after delivery.

Participants/Inclusion and exclusion criteria

Entry requirements: absence of uterus fibroids, lack of history of postpartum hemorrhage, second or third pregnancy, no high risk pregnancy, excessive distension Uterus, lack of deep vein thrombosis, non-use of drugs that affect nerves and Anticoagulant Conditions of non-arrival: manual withdrawal of fetal placenta and curtains, the need for additional treatments for controlling bleeding, Macrosomia, postpartum urinary incontinence

Intervention groups

After leaving the placenta, without a mother's notice (single blind), a 4 minute general massage followed by 2 minutes of specific reflexology in each of the uterus, pituitary, solar circuits will be performed by the researcher through the rotational pressure on each mother's foot. This operation is also repeated at the second hour after childbirth. In the control group, intervention will not take place.

Main outcome variables

General information

Reason for update

The sampling is not finished

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041962N1**

Registration date: **2019-02-04, 1397/11/15**

Registration timing: **prospective**

Last update: **2024-07-25, 1403/05/04**

Update count: **3**

Registration date

2019-02-04, 1397/11/15

Registrant information

Name

Neda Sharifi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-05-31, 1399/03/11

Actual recruitment start date

2019-02-10, 1397/11/21

Actual recruitment end date

2019-07-01, 1398/04/10

Trial completion date

2019-07-01, 1398/04/10

Scientific title

The effect of foot reflexology in the fourth stage of labor on after pain and postpartum hemorrhage

Public title

The effect of reflexology on postpartum pain and postpartum hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclination to participate in research Iranian race Age 18 to 35 years old Lack of uterus of fibroids (based on mother's statement or ultrasonography before giving birth) Having no history of postpartum hemorrhage Pregnancy second or third The gestational age is 42-37 weeks of gestation (based on the first day of the last menstruation or first trimester ultrasound) Singleton Lack of high risk pregnancy (pregnancy hypertension, placental abnormalities such as dexamethasone, placenta perioia, placenta acetate, curium amnio nitis, gestational diabetes mellitus) Unexplained erythematous (polyhydramnios) Cephalic presentation No cuts, burns, fungal infections, varicose veins, warts, corns or numbness in the legs. The absence of contagious skin diseases such as scabies, chicken pox, yellow wounds Lack of deep venous thrombosis Not having fast delivery The second stage is less than an hour No rupture or episiotomy Non-use of non-pharmacological methods to accelerate the first stage of labor Not taking anticoagulants (enoxaparin or heparin during pregnancy) Do not use drugs that affect the nervous system Vaginal delivery (no device)

Exclusion criteria:

Mother's reluctance to continue to work with a researcher Exit manual pairs and embryonic curtains Need additional treatment to control bleeding (prescribing oxytocin over 10 units, methergine, misoprostol, prostaglandin f2a, blood transfusion, surgical procedures, hand search for abdominal patches and curtains) Baby weighs more than 4 kg Postpartum urinary incontinence (according to the mother) No bleeding more than 500 BC after delivery

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: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be available (easy). Then, the research units will be assigned to two intervention and control

groups using randomized systematic allocation and randomly assigned random numbers. How to use a random number table to allocate research units to study groups will be that the researcher will use the random number table to select the first number and then select the next number by up to 80 for the next five digits. The pair numbers represent the test group and the individual numbers representing the control group

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**

Ethical Committee of Gonabad University of Medical Sciences

Street address

Asian Roadside Border, Gonabad University of Medical Sciences

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Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.GMU.REC.1397.079

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

Postpartum hemorrhage, after pain

ICD-10 code

O72

ICD-10 code description

Postpartum hemorrhage

Primary outcomes**1****Description**

Bleeding the fourth stage of labor

Timepoint

An hour and two hours after the intervention

Method of measurement

Bleeding measurement by disposable weighing method and pads, before and after use

2

Description

Severity of after pain

Timepoint

At first, second, third and fourth postpartum

Method of measurement

Visual Scale of Pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After leaving the placenta, without informing the mother, in the intervention group, 4 minutes of massage were performed on each leg of the mother, and then 2 minutes of specific reflexology in each of the uterus, pituitary, solar network is performed in rotational pressure. The time needed for both feet is 20 minutes. This operation is also repeated at the second hour after childbirth.

Category

Prevention

2

Description

The control group received general massage on each foot for 4 min, followed by rotational pressure on a neutral point on the lateral side of the heel (placebo point).for 6 minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bhlol Gonabadi Hospital

Full name of responsible person

Narges bahri

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Saadi Street, Nurse Bolovar, Allameh Bhlol Gonabadi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Seyyed Ali Sajjadi

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Asian Roads, Vice-Chancellor for Research and Technology, Gonabad University of Medical Sciences

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Grant name

Grant code / Reference number

64

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Narjes Bahri

Position

Assistant Professor, Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

For meet the confidentiality of participants

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