# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

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

### Protocol summary

**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 Behnouli 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**
Postpartum hemorrhage;after pain

### 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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Iran (Islamic Republic of)

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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 erythematosus (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**
Ethnical Committee of Gonabad University of Medical Sciences

**Street address**
Asian Roadside Border,Gonabad University of Medical Sciences

**City**
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Razavi Khorasan

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**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**
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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**
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**Position**

Assistant Professor, Reproductive Health

**Latest degree**
Ph.D.

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Midwifery

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## Person responsible for updating data

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MSc student

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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 confidentially 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