Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Auriculotherapy on postpartum hemorrhage and its consequences

Protocol summary

Study aim
Determining the effect of uriculotherapy on postpartum hemorrhage and its consequences in mothers admitted to selected hospitals in Isfahan in 1400

Design
The present study is a two-stage randomized clinical trial (questionnaire) that will be performed on 106 women undergoing normal delivery in two groups (uriculotherapy and control).

Settings and conduct
This study will be performed on women delivering naturally in the labour ward of selected hospital in Isfahan. The intervention group, in addition to receiving routine care, also receives auricular therapy intervention. Auriculotherapy in Oxytocin (posterior pituitary), Uterus and Shenmen points in the left ear and Thalamic, Long 1 and 2 points in the right ear will be performed with the help of Vakaria herbal seeds. These seeds are placed on the mother's ear at the mentioned points in the dilatation stage of ten centimeters. In the ten-centimeter dilatation phase, immediately after the exit of fetus and one hour after the exit of placenta, each side will be pressed for one minute.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having a term pregnancy, Normal delivery, Having normal hemoglobin, Having the consent to participate in the study, No sores or lesions in the ear, No gravid 4 or higher, Live fetus, single pregnancy Not weighing more than 4000 grams of fetus; Non-inclusion criteria: history of coagulation disorders and use of anticoagulants, endocrine and vascular diseases, high-risk pregnancy,history of infertility, history of mental disorders, recent emotional stress.

Intervention groups
The intervention group, in addition to receiving routine care, will also receive auricular therapy intervention, and the control group will receive only routine care.

Main outcome variables
Postpartum hemorrhage; Postpartum blues; Attachment; Breastfeeding pattern; pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091219002889N12**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-22, 1400/12/03**
Update count: **0**

Registration date
2022-02-22, 1400/12/03

Registrant information

Name
Mahboubeh Valiani

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3651 4640

Email address
valiani@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-05-21, 1401/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Auriculotherapy on postpartum hemorrhage and its consequences

Public title
The effect of Auriculotherapy on postpartum hemorrhage and its consequences

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having a term pregnancy Normal delivery No history of bleeding before and during delivery Having normal hemoglobin (11 and above) Having the consent to participate in the study No sores or lesions in the ear No gravid 4 or higher Live fetus Ultrasound-confirmed single pregnancy Not weighing more than 4000 grams of fetus on ultrasound

Exclusion criteria:
history of coagulation disorders and use of anticoagulants endocrine and vascular diseases high-risk pregnancy (Gestational hypertension, gestational diabetes, etc.) history of infertility history of mental disorders (Mother self report) recent emotional stress (death of a close family member in the current pregnancy, divorce, etc.)

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, all mothers who go to the maternity hospital of the selected hospital for delivery will be evaluated by easy sampling method. Then, mothers who meet the inclusion criteria will be randomly divided into two groups: uriculotherapy (intervention) and control. To do this, sealed envelopes will be used. White envelopes are prepared in 106 pieces and the letter A is placed inside 53 of them and the letter B is placed inside 53 of them, and then the lid of the envelopes will be closed. The envelopes are placed in a box. Mothers referred for delivery will take an envelope out of the box after examining the inclusion criteria and will be placed in the intervention or control group according to the words removed. The letter A indicates the intervention group and the letter B indicates the control group. Any envelopes removed by the mother will be removed from the original envelope box.

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
Ethics Committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib Street، Isfahan university of Medical sciences

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2021-10-30, 1400/08/08

Ethics committee reference number
IR.MUI.NUREMA.REC.1400.183

Health conditions studied

1

Description of health condition studied
Postpartum hemorrhage

ICD-10 code
O72

ICD-10 code description
Postpartum hemorrhage

Primary outcomes

1

Description
Postpartum hemorrhage

Timepoint
One hour and 24 hours after delivery

Method of measurement
Plastic graded shan, number and weight of pads used by mother, hemoglobin and hematocrit level

Secondary outcomes

1

Description
Postpartum blues

Timepoint
One day and ten days after delivery
Method of measurement
Edinburgh Postnatal Depression Scale

2

Description
Postnatal Attachment
Timepoint
One day and ten days after delivery
Method of measurement
Maternal Postnatal Attachment Scale

3

Description
Postpartum Pain
Timepoint
One day and ten days after delivery
Method of measurement
Visual Analog Scale

4

Description
Breastfeeding pattern
Timepoint
One day and ten days after delivery
Method of measurement
Interview with mother

Intervention groups

1

Description
Intervention group: In addition to receiving routine care, the intervention group will also receive auricular therapy intervention. To perform uriculotherapy intervention, the researcher first cleansed the mother's ears with an alcohol swab and then stimulated the Oxytocin(posterior pituitary), Uterus and Shenmen points in left ear and Thalamic, Lung1 and 2 points in right ear with the help of Vakaria herbal seeds.These seeds are placed on the mother's ear at the mentioned points in the dilatation stage of ten centimeters. In the ten-centimeter dilatation phase, immediately after the exit of fetus and one hour after the exit of placenta, each seed will be pressed for one minute. This technique will be performed by the researcher for all samples. After 24 hours from the time of delivery, the previous seeds are removed and new seeds are placed in the same places. The mother is taught to press each point for one minute at least 6 to 8 times and utmost every one hour for ten days. Meanwhile, mothers are told that there is no need to press the seeds at nights.
Category
Treatment - Devices

2

Description
Control group: The control group will receive only routine care during delivery and postpartum period.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Shahid Sadoughi Hospital
Full name of responsible person
Dr. Seyed Reza Mortazavian
Street address
Bozorgmehr street, Isfahan Shahid Sadoughi Hospital
City
Isfahan
Province
Isfehan
Postal code
3733181548
Phone
+98 31 3291 2500
Email
fatemetorkian99@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Mansoor Siavash Dastjerdy
Street address
Hezar Jerib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 7898
Email
reasearch@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Valliani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

valiani@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Valiani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Isfahan University of Medical Sciences, Hezar Jerib St.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 0048

Fax

Email

valiani@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Valiani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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City

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Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 0048

Fax

Email

valiani@nm.mui.ac.ir

Web page address

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