

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the effect of uterine massage on the severity of postpartum hemorrhage after cesarean delivery in low-risk patients

Protocol summary

Study aim

Determining the effect of uterine massage on the severity of postpartum hemorrhage in low risk women compared to routine interventions

Design

A clinical trial with a control group without blinding on 82 patients

Settings and conduct

After receiving the ethics approval from the Research Ethics Committee of Yasouj University of Medical Sciences and receiving the approval code from the Iranian Clinical Trials Center, 82 eligible patients were selected to enter the study. They are divided into two groups receiving uterine massage (intervention) and not receiving uterine massage (control) with the same number of 41 people in each group. All interventions and procedures of the country will be performed the same in both groups. Due to the nature of uterine massage intervention, it is not possible to blind the researcher and the patient in this study. In case of postpartum hemorrhage, the relevant measures will be taken according to the national protocol and will be recorded in the relevant questionnaires.

Participants/Inclusion and exclusion criteria

Mother's age between 18 to 34 years
Absence of severe bleeding during cesarean section
Consent of the patient and spouse to participate in the study
Absence of underlying disease
No emergency caesarean section
Singleton pregnancy
Gestational age greater than to 28 weeks
Being in the low-risk group based on risk factors for postpartum hemorrhage
Pre-pregnancy body mass index of the mother less than 30 kg/m²

Intervention groups

In the intervention group: performing uterine massage in the form of placing a hand on the patient's lower abdomen and one hand inside the vagina and stimulating the uterus with repetitive movements. In the intervention group: uterine massage is not performed to prevent uterine bleeding.

Main outcome variables

severity of postpartum hemorrhage after delivery, blood transfusion after delivery, maternal death after delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220630055325N1**

Registration date: **2022-08-16, 1401/05/25**

Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**

Update count: **0**

Registration date

2022-08-16, 1401/05/25

Registrant information

Name

Ali Mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of uterine massage on the severity of postpartum hemorrhage after cesarean delivery in low-risk patients

Public title
Evaluation of the effect of uterine massage on postpartum hemorrhage

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Surgical incision on the skin by the Pfannenstiel method and transverse incision on the uterus by the Kerr method
Absence of heavy bleeding during cesarean section
Consent of the patient and spouse to participate in the study
Absence of underlying disease
No emergency cesarean section surgery
Singleton pregnancy
Not taking certain drugs
Gestational age greater than or equal to 28 weeks
Being in the low-risk group based on risk factors for postpartum hemorrhage including placenta previa, placental abruption, hypertension, macrosomia, non-cephalic presentation, intrauterine infection or use of assisted reproductive technology pre-pregnancy
mother's body mass index less than 30 kg/m²
Normal plt count
Exclusion criteria:
Hb less than or equal to 9 before delivery

Age
From **18 years** old to **34 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the limited randomization method of the block randomization type. Blocking is usually used in order to balance the number of samples assigned to each of the studied groups. This feature helps the researchers to ensure that the number of samples allocated to each of the studied groups is equal in cases where intermediate analyzes are needed during the sampling process. The randomization tool is also used from random sequence generation software, which in addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. For concealment, we use random allocation concealment, which refers to the method used to perform a random sequence on study participants, in such a way that the allocated group is not known before individual allocation. By using sealed opaque letter envelopes with a random sequence, in this

method, each of the random sequences created is recorded on a card and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a 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 Yasouj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

City

Yasouj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.YUMS.REC.1401.042

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

Severity of postpartum hemorrhage

Timepoint

to 24 after delivery

Method of measurement

Questionnaire and check the amount of bleeding after delivery to CC by performing consecutive examination

Secondary outcomes

1

Description

Receive a blood transfusion

Timepoint

Until discharge from the hospital

Method of measurement

Patients documents of receiving or not receiving blood

2

Description

Maternal mortality after childbirth

Timepoint

Until hospital discharge

Method of measurement

Patients documents

Intervention groups

1

Description

Intervention group: In this group, 30 minutes after delivery, the patients are subjected to uterine massage with bimanual technique by a midwife or the researcher to prevent postpartum hemorrhage. A gloved hand is inserted into the vagina and pressed towards the uterus fundus. The other hand is placed above the fundus of the uterus on the abdomen and the uterus is pressed on the hand that is in the vagina. This process takes ten minutes.

Category

Prevention

2

Description

Control group: Not receiving uterine massage in any method

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Hospital of Yasouj

Full name of responsible person

Ali Mirzaei

Street address

Imam Sajjad Hospital, Saheli St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Ali Mirzaei

Position

Researcher

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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