Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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+98 916 474 7357

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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-Boyrahmad

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
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Sponsors / Funding sources

1

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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
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Yasouj University of Medical Sciences
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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