

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sumac capsule on postpartum hemorrhage in women at risk of bleeding

Protocol summary

Study aim

Determining the effect of sumac capsule on postpartum hemorrhage in women at risk of bleeding

Design

Clinical trial with control group, parallel groups, triple blind, randomized.

Settings and conduct

The present study is a triple-blind clinical trial (research unit, researcher, statistical analyst) which is performed on 72 eligible mothers who referred to Torbat Heydariyeh Hospital for vaginal delivery. Eligible mothers are selected in an accessible manner, and would be randomly allocated into intervention and control groups. Sumac and placebo capsules are coded by the assistant professor of pharmacology. Bleeding is measured by weighing disposable Droschit and pads before and after using the drug and at the end of the first, second, third and fourth hours after delivery.

Participants/Inclusion and exclusion criteria

Conditions included: 15-50 years, Tendency to have a normal delivery. Term pregnancy. No history of allergy to sumac. Absence of severe bleeding during childbirth. Conditions not included: Serious postpartum complications. The mother's unwillingness to continue participating in the study. The need for invasive actions and medication to control severe postpartum hemorrhage

Intervention groups

Intervention group: In addition to the routine oxytocin method, is given dry sumac immediately after placental abruption and 2 hours later. Placebo group: In addition to the routine method, will be given placebo (500 mg capsule containing an inert substance (Avisel powder) immediately after placental abruption and 2 hours later.

Main outcome variables

Postpartum hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220314054275N1**

Registration date: **2022-06-23, 1401/04/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-23, 1401/04/02**

Update count: **0**

Registration date

2022-06-23, 1401/04/02

Registrant information

Name

Mahsa Payranj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5222 6016

Email address

payranjm982@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-20, 1401/03/30

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sumac capsule on postpartum hemorrhage in women at risk of bleeding		researcher and professor of statistics, will be revealed that which group has been drugs and placebo.	
Public title	The effect of sumac capsule on postpartum hemorrhage in women at risk of bleeding	Blinding (investigator's opinion)	Triple blinded
Purpose	Treatment	Blinding description	Sumac and placebo capsules are coded by the assistant professor of pharmacology and the researcher is unaware of which drug and which placebo. At the end of the analysis, the researcher and professor of statistics will be revealed that which group has been drugs or placebo.
Inclusion/Exclusion criteria	Inclusion criteria: Written consent to participate in the study Iranian and resident of Torbat Heydariyeh Literacy age range between 15-50 Tendency to have a normal delivery Term pregnancy Beginning of the active phase of labor Achieve a score equal to or greater than 10% of the prognosis of postpartum hemorrhage No major medical illness No history of cesarean section or uterine surgery lack of take Special drugs lack of Grade 3 and 4 rupture lack of severe bleeding during childbirth lack of herbal or chemical drugs before childbirth and during labor and delivery lack of rupture of cervix and uterus lack of labor complications in the active phase of labor lack of Temperatures greater than 38 ° C during the study lack of rupture of fetal membranes for more than 12 hours Lack of fast labor Lack of prolonged labor No history of allergy to sumac, according to the mother's report lack of Cesarean delivery Exclusion criteria: Serious postpartum complications in the mother The mother's unwillingness to continue participating in the study Occurrence of any allergy to sumac Leakage of urine during blood collection Need for invasive actions and medication to control severe postpartum hemorrhage (sample will be recorded and excluded)	Placebo	Used
Age	From 15 years old to 50 years old	Assignment	Parallel
Gender	Female	Other design features	
Phase	3	Secondary Ids	empty
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor - Data analyser	Ethics committees	
Sample size	Target sample size: 72	1	
Randomization (investigator's opinion)	Randomized	Ethics committee	
Randomization description	To ensure an equal number of subjects in the two groups, the permutation block method will be used. For this purpose, we will use the website www.sealedenvelope.com in such a way that a number of 6 and 4 member blocks are accidentally created through the above site. Examples of blocks can be: [ABAB], [ABBAAB], [BBAABA], [BAAABB],...Sumac and placebo capsules are coded by the assistant professor of pharmacology and the researcher is unaware of which drug and which placebo. At the end of the analysis, the	Name of ethics committee	Ethics Committee of Mashhad University of Medical Sciences
		Street address	Qureshi Building University Street, Mashhad, Iran
		City	mashhad
		Province	Razavi Khorasan
		Postal code	9173595199
		Approval date	2022-03-15, 1400/12/24
		Ethics committee reference number	IR.MUMS.NURSE.REC.1401.005
		Health conditions studied	
		1	
		Description of health condition studied	Postpartum haemorrhage
		ICD-10 code	JA43.0
		ICD-10 code description	A condition characterised by excessive loss of blood during the third stage of labour for a vaginal delivery. This condition is caused by uterine atony, trauma, retained placenta, or coagulopathy
		Primary outcomes	
		1	
		Description	The amount of postpartum hemorrhage

Timepoint

at the end of 1, 2, 3 and 4 hours after delivery

Method of measurement

Weighing blood collection bags and blood-soaked pads

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In addition to routine method of oxytocin , intervention group will be given two oral capsules of 500 mg of dry sumac extract with a yield of 30% (equivalent to 1 gram of sumac) immediately after placental abruption and 2 hours later.

Category

Treatment - Drugs

2**Description**

Control group: In addition to the routine method of oxytocin , will be given placebo (500 mg capsule containing an inert substance (Avisel powder) immediately after placental abruption and 2 hours later.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

بیمارستان نهم دی

Full name of responsible person

Dr. Hossein Dinpanah Khoshdereg

Street address

Khorasan Razavi - Torbat Heydariyeh - Ayatollah Kashani Street - in front of Kashani Park

City

Torbat heydariyeh

Province

Razavi Khorasan

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Web page address

<https://www.thums.ac.ir>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayyur Mobarahan

Street address

Qureshi Building University St., Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Payranj

Position

Master's degree student of reproductive health

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Crossroads Doctora, Ibne Sina Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Moradi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Not applicable

Title and more details about the data/document

Publication of research results in the form of scientific article printing

When the data will become available and for how long

data will become available after publication of the article.

To whom data/document is available

The general public and all researchers

Under which criteria data/document could be used

To inform the public about the reduction of postpartum hemorrhage rate in women at risk of bleeding and scientific use based on the article.

From where data/document is obtainable

Dr. Maryam Moradi, Assistant Professor, Mashhad School of Midwifery Nursing, e-mail: moradim@mums.ac.ir

What processes are involved for a request to access data/document

Request to access data/documents would be assessed by the research team.

Comments