Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The effect of Achillea millefolium rectal suppositories on the prevention of postpartum hemorrhage and after pain

Protocol summary

Study aim
Determining the effect of yarrow plant suppositories on the prevention of postpartum hemorrhage and after pain

Design
The clinical trial has a control group with parallel, three-blind, random, phase 3 groups on 100 patients. The rand function of Excel software is used for randomization.

Settings and conduct
Pregnant who refer to Zahra Marzieh Hospital in Isfahan for delivery and entry criteria are selected. The objectives of the research and the freedom of the company are explained. In case of agreement, written informed consent will be taken. Complete the personal information form and review the entry criteria. 100 women Randomly assigned to two groups of Yarrow supp with 20 units of oxytocin and placebo supp with 20 units of oxytocin per liter.participants, researchers, patient caregivers, outcome assessors, data analyzers, and safety committee do not know about the type of supp.

Participants/Inclusion and exclusion criteria
egnant women who refer to Hospital for delivery and have the characteristics of entry criteria People who meet the criteria for entering the study or are discouraged from participating in the study

Intervention groups
Hemoglobin check mother and after the delivery, 20 units of oxytocin per liter of serum give to both groups. In the intervention group, a yarrow rectal supp with a dose of 250 mg is prescribed, and a placebo supp which looks similar to the yarrow suppis prescribed to the control group.these drugs is repeated every 6 hours. To pain, from 2 hours after delivery, the pain intensity is checked using a visual pain scale and recorded، Then it is measured every 6 hours to 24 hours after delivery before and one hour after the administration of yarrow supp and placebo supp.

Main outcome variables
Bleeding, weight of mother and newborn, number of deliveries, abortion, gestational age, labor rupture, water sac rupture time, , hemoglobin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230610058438N1**
Registration date: **2023-07-21, 1402/04/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-21, 1402/04/30**
Update count: **0**

Registration date
2023-07-21, 1402/04/30

Registrant information

Name
Azita Raeisi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3781 7248

Email address
a.raeisi68@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-12, 1402/04/21

Expected recruitment end date
2023-09-12, 1402/06/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of Achillea millefolium rectal suppositories on the prevention of postpartum hemorrhage and after pain

Public title
Investigating the effect of yarrow on bleeding and pain after childbirth

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Entry criteria: written consent to participate in the study, being Iranian, reading and writing, mother's age range between 15-50, desire to have natural childbirth, cephalic presentation, singleton pregnancy, Term pregnancy (38 to 42 full weeks based on LMP or first trimester ultrasound) Obtaining a score equal to or greater than 10% of the nemogram is the prevention of postpartum hemorrhage

Exclusion criteria:
Exclusion criteria include: allergy to yarrow, unwillingness to continue participating in the study, cesarean delivery, history of uterine surgery, use of herbal or chemical drugs before delivery and during labor and delivery. The occurrence of serious complications after childbirth (higher temperature equal to 38 degrees Celsius and higher blood pressure equal to 140/90) contracting a medical disease Heavy bleeding during childbirth, 3rd and 4th degree tears, uterine and cervical tears, use of epidural anesthesia, shoulder dystocia, decollement, require invasive measures or drugs.

Age
From **55 years** old to **15 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Excell software is used to create a random sequence. To create a sequence in a column, study groups (A, B) are entered as follows. In the other column, the number of samples is entered from 1 to 100 (each group has 50 people). Random numbers are generated in the opposite column with the RAND command. Then, by executing the Sort command, the generated random numbers are sorted from small to large. In this way, the assignment of people to groups A and B is done randomly. Finally, based on the random numbers created in the software, cards are created, on one end of which a number is written based on the random sequence created in the software, and on the other side is one of the letters A/B. . Samples choose cards based on the numbers on the cards. Allocation to intervention and control groups is done based on the letters written on the other end of the card and should not be visible to mother and the researcher.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Based on the random numbers created in the software, cards are created, on one end of which a number is written based on the random sequence created in the software, and on the other side is one of the letters A/B. Samples choose cards based on the numbers on the cards. Allocation to intervention and control groups is done based on the letters that are written on the other end of the card and should not be visible to Zao and the researcher. Also, the researcher, the participants, the monitoring committee, the health care workers, the outcome assessor, and the analyst. Data do not know which suppositories contain yarrow or placebo

Placebo
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
Amirieh St. 7th St. second branch of Kausar building

City
Isfahan

Province
Isfehan

Postal code
8174954584

Approval date
2023-06-10, 1402/03/20

Ethics committee reference number
IR.YUMS.REC.1402.039

Health conditions studied

1

Description of health condition studied
postpartum hemorrhage,after pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Postpartum bleeding is considered to be the difference greater than equal to 500 grams before and after use between the weight of the bag used to collect blood and caused by the blood collected in it.
Timepoint
Bleeding volume is measured in the first, second, third and fourth hours after placental discharge
Method of measurement
Blood collection bag, sheet and pad

2

Description
hemoglobin
Timepoint
Before delivery, 6 and 24 hours after delivery
Method of measurement
Laboratory measurement

3

Description
after pain
Timepoint
The amount of after pain at 2, 6, 12, 18, and 24 hours after delivery
Method of measurement
Based on visual pain scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After removal of the placenta and fetal membranes and uterine massage, a yarrow rectal suppository with the scientific name of Achillea millefolium at a dose of 250 mg is prescribed to mothers by the researcher. Then every 6 hours the administration of these drugs is repeated.
Category
Prevention

2

Description
Control group: After removal of the placenta and fetal membranes and uterine massage, a placebo suppository that looks like Yarrow suppository is prescribed by the researcher to the mothers. Then every 6 hours the administration of these drugs is repeated
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahra Marzieh Hospital, Isfahan
Full name of responsible person
Azita Raeisi
Street address
mirieh St., 7th St., 2nd Subdivision, Kosar Building
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Amin Hosseini Mutlaq
Street address
Amirieh St., 7th St., 2nd Subdivision, Kosar Building
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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
Azita Raeisi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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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