

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of effect of rectal suppository of *Plantago Major* and *Anethum Graveolens* on postpartum hemorrhage rate in women at risk of bleeding

Protocol summary

Study aim

Comparison the effect of rectal suppository of *Plantago* and *Anethum graveolens* (Dill) on postpartum hemorrhage (PPH) rate in women at risk of bleeding

Design

The present study is a randomized, triple blind clinical trial with control group and parallel group design, study phase 3 which will be performed on 105 eligible pregnant women.

Settings and conduct

The present study is a triple blind clinical trial (research unit, researcher, and statistician) that is performed on 105 pregnant women who are eligible for vaginal delivery admitted to Umm al-Binin Hospital in Mashhad. The research units are randomly selected and divided into 2 intervention and 1 control groups. In the control group, routine care is taken. In the intervention groups, in addition to routine care, administration of rectal *plantago* supp and *dill* sid supp is carried. The amount of blood will be measured through weighing disposable pads before and after using the drug and at the end of the first, 2th and 4th hours of delivery.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Term pregnancy, normal delivery, a score equal to or greater than 10% of the prediction PPH nomogram. Non Inclusion criteria: medical illness, cesarean section or surgery on the uterus, rupture grade 3 and 4, occurrence of labor complications during labor active phase.

Intervention groups

Intervention group 1: Prescription of rectal *plantago* supp immediately after expulsion of placenta in addition to routine treatment. Intervention group 2: Prescription of *dill* rectal supp immediately after expulsion of placenta in addition to routine treatment. Control group: Oxytocin infusion immediately after expulsion of placenta

Main outcome variables

Postpartum hemorrhage rate

General information

Reason for update

Sampling and research completion dates were added

Acronym

IRCT registration information

IRCT registration number: **IRCT20181027041472N1**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **prospective**

Last update: **2021-11-28, 1400/09/07**

Update count: **1**

Registration date

2019-01-16, 1397/10/26

Registrant information

Name

zahra khojastehfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3872 1568

Email address

khojastehfz961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date

2019-03-19, 1397/12/28
Trial completion date
2019-03-19, 1397/12/28

Scientific title
Comparison of effect of rectal suppository of Plantago Major and Anethum Graveolens on postpartum hemorrhage rate in women at risk of bleeding

Public title
The effect of Plantago Major and Anethum Graveolens rectal suppository on postpartum hemorrhage

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Having tendency and written consent to participate in the study. Being Iranian and living in Mashhad Ability to read and write Mothers' age range between 15-50 years tendency to normal delivery term pregnancy Start the active phase of labor The score equal to or greater than 10% of prediction postpartum hemorrhage nomogram
Exclusion criteria:
medical and psychological illness history of cesarean section or surgery on the uterus Consumption the specific medications severe bleeding during and after delivery rupture grade 3 and 4 uterus and cervical rupture using herbal or chemical drugs before or during labor complications of childbirth in the active phase of labor temperature more than 38 ° C during the study rupture of embryonal membrane for more than 12 hours

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**
Actual sample size reached: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Table of random numbers using the spss software

Blinding (investigator's opinion)
Triple blinded

Blinding description
In intervention groups such as Plantago Major and Anethum Graveolens suppositories are apparently identical, therefore, the subjects under study and evaluators, analysts and sample allocators into two groups are blind , but in the control group only the analysts and sample allocators into three groups are blind.

Placebo

Not used
Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Science
Street address
Quraishi Building, Daneshgah street, Mashhad, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9173595199

Approval date
2018-10-06, 1397/07/14

Ethics committee reference number
IR.MUMS.NURSE.REC.1397.043

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 rate

Timepoint
Before intervention; after 1st, 2nd and 4th hours after delivery

Method of measurement
Through weighing blood collection bags and disposable pads

Secondary outcomes
empty

Intervention groups

1

Description

Control group: oxytocin infusion immediately after the expulsion of placenta, according to the country's instruction.

Category

Prevention

2

Description

Intervention group 1: immediately after the expulsion of placenta and fetal membranes and uterine massage, the pregnant women will receive rectal plantago major suppository every 30 min in addition to oxytocin infusion and in order to reach the effective dose, the suppository will be used in 5 doses.

Category

Prevention

3

Description

Intervention group 2: immediately after the expulsion of placenta and fetal membranes and uterine massage, the pregnant women will receive rectal dill suppository every 30 min in addition to oxytocin infusion and in order to reach the effective dose, the suppository will be used in 5 doses.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin Women's Hospital

Full name of responsible person

Dr Fatemeh Tara

Street address

Omolbanin Women's Hospital, Ayatollah Behjat 16 street, Zarineh Cross-rod

City

Mashhad

Province

Razavi Khorasan

Postal code

0702409278

Phone

+98 51 3223 1061

Email

TaraF@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Between Shahid Javan and Al-Shahidi Squares, Shahid Fakoori Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9919191778

Phone

+98 51 3841 2081

Email

TafaghodiM@mums.ac.ir

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

Zahra khojastehfard

Position

MSc Student in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Ebnesina Ave, Mashhad, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

khjastehfz961@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Golmakani

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Ebnesina Ave,
Mashhad, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

GolmakaniN@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Khojastehfard

Position

MSc student in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Ebnesina Ave,
Mashhad, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 917 416 4984

Email

khojastehfz961@mums.ac.ir

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