Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
khojastehfz961@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