Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating The effect of plantago capsules on postpartum hemorrhage after normal vaginal delivery

Protocol summary

Study aim
Investigating The effect of plantago capsules on postpartum hemorrhage after normal vaginal delivery i

Design
his study is a randomized, double-blind experimental work with a control group that will be conducted in Nik Nafs maternity hospital in Rafsanjan city. Mothers are randomly selected using a ball

Settings and conduct
This study is a double-blind clinical trial conducted in Rafsanjan city

Participants/Inclusion and exclusion criteria
nclusion criteria: 1. Gestation age 37-42 weeks 2. Number of pregnancies less than 3 3. Having a single fetus and cephalic presentation 4. Baby weight between 2500-4000 grams 5. Absence of pregnancy complications (polyhydramnios, bleeding and pregnancy blood pressure) 6. No history of cesarean section and uterine surgery or postpartum bleeding 7. Not suffering from systemic diseases (diabetes, hypothyroidism, coagulation disorders) 8. Not using magnesium sulfate during pregnancy 9. Absence of wide episiotomy (3rd and 4th degree tear) during the second stage of labor 10. The normal length of the first, second and third stages of labor 11. Not using herbal or chemical medicines before delivery and during labor and delivery 12. Occurrence of severe bleeding during childbirth (more than 500 cc) and receiving drug treatment Exit criteria: 1. Mother's unwillingness to continue participating in the study 2. Cause any sensitivity to Barhang 3. Metritis or postpartum infections 4. Using other drugs to prevent bleeding 5. Forgetting more than 48 hours of taking capsules

Intervention groups
People will be divided into two intervention and control groups. In the intervention group (40 people), from 24 hours after delivery, two capsules of barhang and The control group (40 people) will receive placebo capsules containing corn starch powder.

Main outcome variables
Barhang capsule consumption;Bleeding score;Number of days of bleeding Age;Level of Education;Job

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240429061586N1**
Registration date: **2026-01-05, 1404/10/15**
Registration timing: **retrospective**

Last update: **2026-01-05, 1404/10/15**
Update count: **0**

Registration date
2026-01-05, 1404/10/15

Registrant information

Name
Narges Khodadadpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3425 2173

Email address
info@rums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-26, 1403/07/05

Expected recruitment end date
2025-06-01, 1404/03/11

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The effect of plantago capsules on postpartum hemorrhage after normal vaginal delivery

Public title

Investigating The effect of plantago capsules on postpartum hemorrhage after normal vaginal delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestation age 37-42 weeks Number of pregnancies less than 3 Having a single embryo and cephalic presentation The weight of the baby is between 2500-4000 grams Absence of pregnancy complications (polyhydramnios, bleeding and pregnancy blood pressure) No history of cesarean section and uterine surgery or postpartum bleeding Not suffering from systemic diseases (diabetes, hypothyroidism, coagulation disorders) Not taking magnesium sulfate during pregnancy Absence of a wide episiotomy (grade 3 and 4 tears) during the second stage of labor The normal length of the first, second and third stage of labor Not using herbal or chemical medicines before delivery and during labor and delivery Severe bleeding during delivery (more than 500 cc) and receiving medical treatment

Exclusion criteria:

Presence of pregnancy complications (polyhydramnios, bleeding and pregnancy blood pressure) history of cesarean section and uterine surgery or postpartum bleeding suffering from systemic diseases (diabetes, hypothyroidism, coagulation disorders) taking magnesium sulfate during pregnancy Presence of a large episiotomy (grade 3 or 4 tear) during the second stage of labor Abnormal length of the first, second, and third stages of labor using herbal or chemical medicines before delivery and during labor and delivery Severe bleeding during delivery (more than 500 cc) and receiving medical treatment

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

thers are placed in one of the two groups of receiving Barhang capsule or control by random allocation, in such a way that the first person takes one of the two balls on which the letter a or b is written, and the next person is in the opposite group and until the end of the sample The acquisition continues in the same way.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants is not aware of which group they are in, and the data analyst is not aware of which group the data belongs to. Plantain seed powder and lactose are filled into capsules of the same color and size and finally packaged in identical cans. Each patient takes two capsules daily, 12 hours apart, for 2 weeks. The cans of medication are coded by the pharmacist. participants and the analyst are unaware of the contents of the cans.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Nurse Street

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2024-09-14, 1403/06/24

Ethics committee reference number

IR.RUMS.REC.1403.085

Health conditions studied

1

Description of health condition studied

postpartum hemorrhage after normal vaginal delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

postpartum hemorrhage after normal vaginal delivery

Timepoint

Checking the amount of bleeding 24 hours after delivery for 40 days

Method of measurement
PBAC form(PBAC Scoring System)

Secondary outcomes

1

Description
postpartum hemorrhage after normal vaginal delivery
Timepoint
Bleeding rate 24 hours after delivery for 40 days
Method of measurement
PBAC form

Intervention groups

1

Description
Intervention group:In the intervention group (40 people), starting 24 hours after delivery, two capsules of plantain (containing 750 mg of plantain seed powder obtained by hydroalcoholic method and preserving its astringent compounds) are administered orally daily for 2 weeks. The method of preparing the capsules is as follows: plantain seeds will be obtained from an apothecary in Rafsanjan city. The seeds purchased at the Kerman Faculty of Traditional Medicine are examined by a botanist and after confirming the genus and species name, a herbarium number is assigned to them. In order to initially check the quality of the purchased samples, the amount of total ash, acid-insoluble ash, moisture, and percentage of extract obtained from the plant are determined using the methods mentioned in the herbal pharmacopoeia. To prepare the final product, the plantain seeds are first carefully examined to ensure that they do not contain foreign components or impurities. The seeds will be powdered with an electric grinder. The seed powder is filled into size 2 capsules with a long base using a manual capsule filling machine. Each capsule contains 750 mg of plantain. Plantain seed powder and lactose are filled into capsules of the same color and size and finally packaged in identical cans. Each patient takes two capsules daily at 12-hour intervals for 2 weeks. The medicine cans are coded by the pharmacist and the obstetrician and analyst are unaware of the contents of the cans. During 40 days, by forming a group in cyberspace, individuals are followed up daily for taking the medicine and filling out the relevant form and the explanations are reminded again and at the end of this 40-day period, the filled forms are delivered to comprehensive health centers. In the case of samples that are not able to visit health centers, they will also be followed up separately and the forms will be delivered in person. The average days and bleeding score in the two intervention and control groups are evaluated and compared.
Category
Treatment - Drugs

2

Description
Control group:The control group (40 people) receives placebo capsules containing lactose. Lactose-containing capsules are used as placebo. Plantain seed powder and lactose are filled into capsules of the same color and size and finally packaged in identical cans. Each patient takes two capsules daily at 12-hour intervals for 2 weeks. The drug cans are coded by the pharmacist, and the nurse and the analyst do not know the contents of the cans. During 40 days, by forming a group in cyberspace, people are followed up daily to take the drug and fill out the relevant form, and the explanations are reminded again, and at the end of this 40-day period, the filled forms are delivered to comprehensive health centers. In the case of samples that are not able to visit health centers, they will also be followed up separately and the forms will be delivered in person. The average days and bleeding score in the two intervention and control groups are evaluated and compared.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nik Nafs Maternity Hospital Rafsanjan
Full name of responsible person
Dr.Mirmotalebi
Street address
Shahada St
City
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Province
Kerman
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7716648995
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Email
Niknafs@rums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
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Postal code

7718796755

Phone

+98 34 3425 5900

Email

Parstari@rums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Narges .Khodadadpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Email

nargeskhodadadpour1400@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Narges Khodadadpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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nargeskhodadadpour1400@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Narges Khodadadpour

Position

Consultant

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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nargeskhodadadpour1400@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

In this study, personal information cannot be published, but information about the results and analysis is accessible

When the data will become available and for how long

Access starts 7 months after publication

To whom data/document is available

Researchers working in academic institutions and interested students can access the information

Under which criteria data/document could be used

Data can be used by mentioning the source

From where data/document is obtainable

For people, if they refer to my email, if the request is allowed, an email will be sent within a few days. nargeskhodadadpour1400@yahoo.com

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

It can be accessed by visiting Rafsanjan University of Medical Sciences or a personal email will be sent within a few days if allowed

Comments