

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

To determine the effect of oral syrup of Plantago on postpartum hemorrhage

Protocol summary

Summary

Purpose: To determine the effect of oral syrup of Plantago on postpartum hemorrhage Design: Random sampling using random allocation software, double-blind, placebo-controlled Methods: A) The study population: The study population includes all women that will give birth in Ganjavian maternity clinic of Dezful, in 2017. The sample: The study sample consists of all eligible women that will give birth in Ganjavian maternity clinic of Dezful, in 2017. Inclusion criteria: Age of 20 to 35 years old, less than 3 pregnancies, gestational age between 37 to 42 weeks, singleton pregnancy with cephalic presentation and a fetal weight between 2,500 to 4,000 grams, no pregnancy complications, no history of cesarean section or surgery on the uterus or postpartum hemorrhage, no systemic diseases, no magnesium sulfate consumption during pregnancy, clarity of the amniotic fluid during the first stage of labor, lack of wide episiotomy (rupture of grade 3 and 4) during the second stage of labor, normal duration of the first, second and third stages of labor, no severe postpartum hemorrhage, no severe hemorrhage during labor. Exclusion criteria: Hemorrhage during labor, unwillingness to continue to participate in the study, allergy to Plantago major, caesarean section. Sample size: 94 people B) Intervention: Consumption of oral syrup of Plantago major and placebo. C) The primary outcome or studied outcomes: The effect on the volume of postpartum hemorrhage in the intervention group

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201505283226N9**

Registration date: **2017-08-24, 1396/06/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-24, 1396/06/02

Registrant information

Name

Mahrokh Dolatian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

m_dolatian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-07-21, 1396/04/30

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To determine the effect of oral syrup of Plantago on postpartum hemorrhage

Public title

effect of oral syrup of Plantago on postpartum hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age of 20 to 35 years old, less than 3 pregnancies, gestational age between 37 to 42 weeks, singleton pregnancy with cephalic presentation and a fetal weight between 2,500 to 4,000 grams, no pregnancy complications, no history of cesarean section or surgery on the uterus or postpartum hemorrhage, no systemic diseases, no magnesium sulfate consumption during pregnancy, clarity of the amniotic fluid during the first stage of labor, lack of wide episiotomy (rupture of grade 3 and 4) during the second stage of labor, normal duration of the first, second and third stages of labor, no severe postpartum hemorrhage, no severe hemorrhage during labor. Exclusion criteria: Hemorrhage during labor, unwillingness to continue to participate in the study, allergy to Plantago major, caesarean section.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Random sampling was done using random allocation software.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Nursing & Midwifery & Pharmacy Ethical Committee of Shahid Beheshti University of Medical Science

Street address

Yaman street, next to Taleghani hospital, Shahid Beheshti University of Medical Sciences, Post code: 198396-3113

City

Tehran

Postal code

1985717443

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

IR.SBMU.PHNM.1395.578

Health conditions studied

1

Description of health condition studied

Postpartum haemorrhage

ICD-10 code

O72.1

ICD-10 code description

haemorrhage after delivery of fetus or infant

Primary outcomes

1

Description

The amount of bleeding after delivery of the placenta and fetus

Timepoint

Every one hour for six hours

Method of measurement

Weighing pads and gowns in the first, second, third and sixth hour.

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Control group: 20 units of oxytocin in 1000 cc of Ringer's solution and 100 cc of the placebo syrup will be administered to the women in labor in two doses of immediately and 30 minutes after the expulsion of the placenta and the fetus.

Category

Placebo

2

Description

Intervention group: 20 units of oxytocin in 1000 cc of Ringer's solution and 100 cc of Plantago major extract 20% will be administered to the women in labor in two doses, one immediately and one 30 minutes after the expulsion of the placenta and the fetus.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Ganjavian city of Dezful

Full name of responsible person

Dolatian Mahrokh

Street address

Yaman street, next to Taleghani hospita, Shahid Beheshti University of Medical Sciences, Post code:198396-3113

City

Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Shahid Beheshti University of Medical Science

Full name of responsible person

Doctor M.Dolatian

Street address

Yaman street, next to Taleghani hospita, Shahid Beheshti University of Medical Sciences, Post code:198396-3113

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-Chancellor for Research of Shahid Beheshti University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Mahrokh Dolatian

Position

by research PhD / Assistant Professor / Faculty

Other areas of specialty/work

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahrokh Dolatian

Position

by research phd /assistant professor / faculty

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of medical Sciences

Full name of responsible person

Negin Nejati

Position

Masters student of Midwifery

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty