

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation effect of purslane seed capsul on postpartum hemorrhage and after pain in multiparous mothers

Protocol summary

Study aim

Determining the effect of purslane seed capsule on postpartum hemorrhage and after pain in multiparous mothers

Design

A clinical trial with a probable sample size of 70 members with control group, with parallel groups, triple blind and randomized

Settings and conduct

Multiparous mothers will be selected in the maternity ward of Imam Khomeini Hospital in Shirvan. The coding of the capsules by the pharmacist. The researcher and participants unaware from the type of groups. Participants receive one A or B capsule every 8 hours in the first 24 hours after exit placenta. Measure bleeding, in the first 6 hours and after pain in the first 24 hours of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Second to fifth delivery, Lack of medical illness, No high risk pregnancy, No history of post partum hemorrhage, No history cesarean section or uterine surgery, No bleeding in the labor, Normal second and third stage of delivery, Second degree rupture And less perineal, No abnormal placenta. And exclusion criteria include: Mother suffers from serious complications after delivery, Requires additional treatment to control hemorrhage, Do not breastfeeding in the third or fourth stages of delivery, Using from herbal or chemical drugs to relieve pain.

Intervention groups

The intervention group was treated with purslane seed capsule prepared by the Pharmacology Department of Mashhad University contains 500 mg of purslane seed extract. One number immediately follows the third stage of delivery and then every 8 hours during the first 24 hours after delivery. The control group during this period with same condition, the placebo capsule containing starch, prepared by the Pharmacology Department of Mashhad University will be used. If mothers complain

from after pain, they will be given a 250 mg mefenamic acid capsule.

Main outcome variables

after pain ; hemorrhage volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181007041266N1**

Registration date: **2018-12-28, 1397/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-28, 1397/10/07**

Update count: **0**

Registration date

2018-12-28, 1397/10/07

Registrant information

Name

mahjoubeh ramezani motlagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3621 0469

Email address

ramezanimm951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation effect of purslane seed capsul on postpartum hemorrhage and after pain in multiparous mothers

Public title

Investigation effect of purslane seed on postpartum hemorrhage and after pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being iranian Mother tend to natural delivery Mother's age between the ages of 18 - 35 years Healthy and alive fetus Single pregnancy with cephalic presentation Age Pregnancy 37-42 weeks Normal Body Mass Index(BMI) before or during the first trimester of pregnancy Fetus weight 2500-4000 gram Second to fifth delivery Lack of medical illness No high risk pregnancy No psychiatric illness requiring drug use No regular use of narcotic during pregnancy No history of post partum hemorrhage Is not delivery with medicinal analgesia No use of uterine relaxants during labor No history cesarean section or uterine surgery Is not rapid labor Non-narcotic addiction based on person's statement Natural delivery and without a device No history of uterus or cervical rupture No bleeding in the labor Normal second and third stages of delivery Rupture of the membranes less than 12 hours until delivery Second degree rupture and less perineal No abnormal placenta Non stretch excessive of uterin during pregnancy

Exclusion criteria:

Mother suffers from serious complications after delivery Requires additional treatment to control hemorrhage Do not breastfeeding in the third or fourth stages of delivery Using herbal or chemical drugs to relieve pain The mother insisted on early discharge 24 hours after delivery

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of mothers is done by simple randomization with random numbers table in sealed envelope. That's 70 pack contains 35 packages

containing four capsules of the placebo (code B) and 35 packages containing four purslane seed capsules (code A).The even numbers for the intervention group (code A) and the odd numbers for the control group (code B) Is considered.Encoding of capsules is done by the pharmacist,The capsules look quite similar, and the researcher and the mothers are unaware of the code of the groups.Participants will randomly pick up a package of sealed envelopes in either of the two groups A or B.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The current study is a three-blind randomized clinical trial.So that the participant , researcher and data analyst are not aware of any individuals located in the studied groups and control.Purslan seed and placebo capsules are completely similar in appearance and are prepared and coded by the pharmacist.The researcher is unaware of the code of the capsules and the participants are unaware of the capsule contents due to the similarity of the capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences.,Daneshgah Ave.,Mashhad.,Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2018-07-14, 1397/04/23

Ethics committee reference number

IR.MUMS.REC.1397.111

Health conditions studied**1****Description of health condition studied**

After pain delivery

ICD-10 code

Z39

ICD-10 code description

Encounter for maternal postpartum care and examination

2

Description of health condition studied

Postpartum hemorrhage

ICD-10 code

O72.1

ICD-10 code description

Other immediate postpartum hemorrhage

Primary outcomes

1

Description

after pain

Timepoint

During the first 24 hours of delivery - every 8 hours - an hour before and one hour after the intervention

Method of measurement

Measuring instrument for pain, vas scale

2

Description

Hemorrhage volume

Timepoint

The first 6 hours of delivery - Every one hour .

Method of measurement

Chinese digital scales

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A capsule of 500 mg of purslane seeds prepared in Department of Pharmacology Mashhad University immediately and then every 8 hours after delivery in the first 24 hours after delivery.

Category

Treatment - Drugs

2

Description

Control group: A 500 mg capsule of starch powder prepared in Department of Pharmacology Mashhad University immediately and then every 8 hours after delivery in the first 24 hours after delivery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Hospital

Full name of responsible person

Mahjoobeh Ramezani Motlagh

Street address

Imam khomeini Hospital.,Imam Reza Street.,Shirvan.,North Khorasan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

School of Pharmacy, University Campus(Pardis) ,Vakil Abad Blvd.

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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

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

Mahjoobeh Ramezani Motlagh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person

Nahid Golmakani

Position

Midwifery Master's Degree

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available