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 pospartum 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)

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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
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Imam khomeini Hospital.,Imam Reza Street.,Shirvan.,North Khorasan
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Sponsors / Funding sources

1

Sponsor
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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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Position
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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