Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of Punica granatum var. pleniflora (Persian Gulnar) ointment on pain severity and healing of episiotomy wound in primiparous women

Protocol summary

Study aim

Determination the effect of Punica Granatum var. pleniflora (Persian Gulnar) ointment on pain severity and healing of episiotomy wound in primiparous women referred to Niknafs maternity hospital of Rafsanjan in 2022

Design

Randomized Clinical Trial with one intervention groups and one control group; Three blindsides; Parallel groups; Permuted block randomization

Settings and conduct

The statistical population of the research; Includes all nulliparous pregnant women referring tomaternity hospital in Rafsanjan. The sample size will be estimated based on the statistical formula (45 people in each group). This research will be a triple-blind study. In order to blinding, the pharmacist will be asked to define the medicines and placebo with group A_B and will put the prescription of them inside each package. Blinding will be done for the researcher, samples, clinical caregiver, and analyzer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Inform consent for participant in the study; Willingness to normal vaginal delivery,Selection of Niknafs Maternity Center of Rafsanjan as the place of delivery; Mother age between 18-35 years; Pregnancy age: 38 weeks; Single-fetal with a cephalic presentation based on the latest ultrasound results; primiparous women; Iranian nationality; vaginal delivery with median or medio laterl incision; BMI 18/5-30 Exclusion criteria: Sensitivity to Punica granatum var. pleniflora; known history of psychological illness; History of psychological problems during 6 month ago Consumption of Antidepressant medication; Drug consumption

Intervention groups

The intervention group apply Persian Gulnar ointment and the control group apply usrine ointment from 2 hours after delivery every 12 hours as a fingertip on the episitomy

Main outcome variables

The mean intensity of pain, healing episiotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044248N7**
Registration date: **2023-03-20, 1401/12/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-20, 1401/12/29**
Update count: **0**

Registration date

2023-03-20, 1401/12/29

Registrant information

Name

Zahra Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Punica granatum var. pleniflora (Persian Gulnar) ointment on pain severity and healing of episiotomy wound in primiparous women

Public title

Evaluation the effect of Punica granatum var. pleniflora (Persian Gulnar) ointment on pain severity and healing of episiotomy wound

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inform consent for participant in the study Willingness to normal vaginal delivery Selection of Niknafs Maternity Center of Rafsanjan as the place of delivery Mother age between 18-35 years Pregnancy age: 38 weeks based on reliable first-trimester ultrasound or last menstrual period Single-fetal with a cephalic presentation based on the latest ultrasound results primiparous women Iranian nationality vaginal delivery with median or medio laterl incision BMI 18/5-30

Exclusion criteria:

Sensitivity to Punica granatum var. pleniflora known history of psychological illness History of psychological problems during 6 month ago Consumption of Antidepressant medication Drug consumption

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals who will have the inclusion criteria will be selected with the Convenience Sampling method. The Permuted block randomization will be used to allocate people to two groups. In this study, nine blocks (every block has 10 paces) will be created, so that after determining Individuals who will have the inclusion criteria, the first 10 people who enter the study will be divided intotwo groups randomly (assigning 5 people to each group), then the next 10 people will be divided into two groups randomly in the same way, and this method will be continued until the last block. The output of the software will be English letters (A& B) and each letter will be the representative of one of the intervention or control groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

At first, participants will be justified about the study, and will be informed consent will be taken. For blinding, the pharmacist will be asked to identify the medicine and placebo with the A_B group and the prescription in each package will be placed. So that the researcher would not know about the content of packages (medicine or placebo). The medicine is also will be given to participants as A or B , and participants will not be informed of the content of packages (medicine or placebo). This blinding will also be available for the analyzer, and after finishing the statistical analysis the content of packages (medicine or placebo) will be asked from pharmacists.

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

Emam Ali Blvd, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

77179335777

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.RUMS.REC.1400.227

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of pain
Timepoint
Determination of intensity of pain score before applying the ointment, fifth and tenth after delivery
Method of measurement
Visual Analogue Scales of intensity pain

Secondary outcomes

1

Description
healing of episiotomy
Timepoint
Determination of healing of episiotomy before applying the ointment, fifth and tenth after delivery
Method of measurement
REEDA

Intervention groups

1

Description
Intervention group apply as much as a fingertip 5% of Persian Gulnar ointment made by SHahid Beheshti School of Pharmacy in Tehran 2 hours after delivery on the episiotomy site
Category
Treatment - Drugs

2

Description
Control group apply as much as a fingertip of userin ointment made by SHahid Beheshti School of Pharmacy in Tehran 2 hours after delivery on the episiotomy site
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nik Nafs Maternity center of Rafsanjan
Full name of responsible person
Zohre Sahebi
Street address
No.38, 40th Alley, Meraj Shomali Aven
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Reza Vazirinezhad
Street address
Deputy of research and technology, Building Num 3, Central Organization of University of Medical Sciences, Imam Ali Blvd
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vcrt@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
Maryam Azarian far
Position
Midwifery
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Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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
Confidentiality of information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable