

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 to maternity 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 episiotomy

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)

Phone

+98 34 3425 5900

Email address

z.saghafi@rums.ac.ir

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

City

Rafsanjan

Province

Kerman

Postal code

7719678375

Phone

+98 913 191 0362

Email

sahebizm@gmail.com

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

City

Rafsanjan

Province

Kerman

Postal code

7718146890

Phone

+98 34 2834 7200

Email

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

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

NO.1, Keshavarz 2 Alley, Sharaf Abad Ave

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591637816

Phone

+98 74 3344 4656

Email

azarian.maryam.98@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Zahra Saghafi

Position

Totur

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

nursing and midwifery scool, sahely Blvd, Motahary street

City

Rafsanjan

Province

Kerman

Postal code

7718145056

Phone

+98 34 2834 7100

Email

z.saghafi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Hossein GHaedamini

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Midwifery

Street address

No.30,15th Yadegar Alley, Yadegar Emam Ave, Yadegar Emam Town

City

Rafsanjan

Province

Kerman

Postal code

7714186759

Phone

+98 34 3434 0454

Email

ghaedaminih@gmail.com

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