

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of quince seed mucilage on perineal pain and healing following episiotomy: a randomized, double-blind, placebo-controlled study

Protocol summary

Study aim

Determining the effect of quince seed mucilage on perineal pain and healing following episiotomy

Design

A double-blinded, randomized, placebo controlled clinical trial with parallel groups

Settings and conduct

This study is a double-blinded clinical trial that will be conducted in Motazedi Hospital affiliated to Kermanshah University of Medical Science. The prepared cream and placebo are made in a similar package with a different code that the pharmacist will be aware of. Patients are also coded according to the blocking method and the ointment will be given in two coded groups.

Participants/Inclusion and exclusion criteria

Entry requirements: Primigravida women with episiotomy, cephalic presentation and term pregnancy.
Non-entry conditions: Difficult delivery, severe postpartum hemorrhage and occurrence of any side effects during the intervention.

Intervention groups

Intervention group 1 (seed to mucilage group): people in this group will use quince seed mucilage at the episiotomy site for 14 days. Intervention group 2 (control group): People in this group will use placebo at the episiotomy site for 14 days.

Main outcome variables

Perineal pain and healing following episiotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160427027633N9**

Registration date: **2023-08-05, 1402/05/14**

Registration timing: **prospective**

Last update: **2023-08-05, 1402/05/14**

Update count: **0**

Registration date

2023-08-05, 1402/05/14

Registrant information

Name

Foruzan Sharifipour

Name of organization / entity

Kermanshah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of quince seed mucilage on perineal pain and healing following episiotomy: a randomized, double-blind, placebo-controlled study

Public title

Investigating the effect of quince seed mucilage on perineal pain and healing following episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First pregnancy Vertex presentation Single and term pregnancy The normal body mass index of the mother is between 19.5 and 24.9 Uncomplicated delivery Mediolateral episiotomy Willingness to cooperate

Exclusion criteria:

Dystocia Use of instrumental delivery Third and fourth degree perineal tears Any disease in mother and newborn Withdrawal of participants during the study Sever postpartum hemorrhage Any lesion or skin infection in the perineum Occurrence of any side effects during the intervention Use of other herbal or medical creams to heal the episiotomy during the intervention

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

The mothers will be randomly assigned in to 2groups in order to Block random allocation method with block size of 4, and ratio of 1:1. It works by randomizing participants within blocks such that an equal number are assigned to each treatment. This will be done with Epi Info™ 6.0 software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The quince seed mucilage and placebo are coded in the same shape and size in two tubes so that only the pharmacist will be aware of the tube content. The researcher, clinical evaluator and statisticians will not be aware of this coding.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blvd., Central Building of Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2023-07-04, 1402/04/13

Ethics committee reference number

IR.KUMS.REC.1402.156

Health conditions studied

1

Description of health condition studied

episiotomy

ICD-10 code

O90.1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes

1

Description

Perineal pain

Timepoint

1, 7 and 14 days after delivery

Method of measurement

VAS pain visual analog scale

Secondary outcomes

1

Description

Episiotomy site healing

Timepoint

1, 7 and 14 days after delivery

Method of measurement

Rida scale

Intervention groups

1

Description

Intervention group: quince seed mucilage . After mucilage preparation by the pharmacist, researcher and research assistant attends Motazedi Hospital maternity ward. Inclusion criteria will be entered into the study

after obtaining written consent. Primiparous women undergoing mediolateral episiotomy will be selected and randomly divided in to two groups: placebo and mucilage and will be coded. Perinatal hygiene training will then be given to all two groups and they will be asked to apply the drug three times daily after rinsing with water and continue for up to 14 days. During this time, the researcher calls to participants by telephone and will be excluded if the drug is not used properly or if complications occur. Then the perineum healing and pain will be examined in the first, seventh, and fourteenth days of peurperium at Razi Hospital in Ahvaz. The VAS and REEDA criteria will be evaluated.

Category

Treatment - Drugs

2

Description

Control group: Placebo. The action is according to the intervention group. The gel formulation used in the placebo group (placebo gel) has all the characteristics of the medicinal gel of quince seed mucilage in terms of the components of the formulation (minus the active ingredient of quince seed mucilage). It contains different proportions of carbomer 934P, ethylene glycol and ethanol. After the preparation of the placebo by the pharmacist, the researcher and the research assistant attended the maternity ward of Motazadi Hospital and asked the eligible women to apply it three times a day after washing the perineum with lukewarm water and continue this for 14 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motazadi Hospital

Full name of responsible person

Foruzan Sharifipour

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Ferdowsi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Sirus Jalili

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Foruzan Sharifipour

Position

Asistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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