

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of topical grape seed cream on episiotomy wound healing in primiparous women: a double-blind randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of grape seed topical cream on episiotomy wound healing

Design

Random allocation in a simple way, people are placed in two groups (70 women) using the Rand list software. Grape cream and placebo cream will be made by the pharmacist and both grape cream and placebo will be coded (A, B). The research unit and the researcher will not know the type of medicine in the cans of Kedar. The measurement of episiotomy wound healing is done using the healing control form (Rida scale) in 24 hours after delivery, on the 7th and 14th day after delivery.

Settings and conduct

Affiliated hospitals of Ahvaz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Term pregnancy (37-42) 2. A single child 3. Age 18 to 35 years 4. Primates 5. Being literate in reading and writing 6. Absence of obesity after childbirth 7. Willingness to participate in the study
Exclusion criteria: 1. Having a special diet 2. Having a specific disease 3. Allergy to herbal medicines and the use of medicines that interfere with wound healing 4. Having a symptomatic infection in the vagina and vulva 5. Having lesions of the anus, vulva and mesentery, hematoma during hospitalization 6. Consumption of cigarettes, alcohol and drugs 7. Disturbance in the stages of childbirth and instrumental delivery 9. Re-manipulation of perineum after childbirth and extension of episiotomy 10. Failure to use medicine regularly 11. Patient's refusal to continue participating in the study

Intervention groups

Primiparous women with episiotomy using grape seed ointment.

Main outcome variables

Episiotomy wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221227056938N2**

Registration date: **2023-04-28, 1402/02/08**

Registration timing: **prospective**

Last update: **2023-04-28, 1402/02/08**

Update count: **0**

Registration date

2023-04-28, 1402/02/08

Registrant information

Name

Fatemeh Razavinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 210 3403

Email address

fatemehrazavinia15@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical grape seed cream on episiotomy wound healing in primiparous women: a double-blind randomized controlled clinical trial

Public title

The effect of topical grape seed cream on episiotomy wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term pregnancy (37-42) primiparous singleton Age 18 to 35 years Being literate in reading and writing Absence of obesity after childbirth (BMI of the samples should not be higher than 29, measured with the same scale) Willingness to participate in the study

Exclusion criteria:

Having a special diet Having a specific disease (anemia, cardiovascular diseases, diabetes, immune, liver, depression and active skin disease, history of diseases that interfere with wound healing, chronic constipation) Allergy to herbal medicines and the use of medicines that interfere with wound healing Having a symptomatic infection in the vagina and vulva (infectious discharge, itching, burning) Having lesions of the anus, vulva and mesentery, hematoma during hospitalization Smoking, alcohol and drugs Disturbance in the stages of childbirth (prolongation of the stages of childbirth and dystoshia) and instrumental delivery (use of vacuum) Heavy bleeding after childbirth Re-manipulation of perineum after childbirth and extension of episiotomy Not using medicine regularly Patient's refusal to continue participating in the study

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by the available method, in such a way that pregnant women after delivery who refer to the hospital of Ahvaz University of Medical Sciences due to candidal vaginitis and are eligible to enter the study are selected. The research units will be assigned to two intervention and control groups using the random block method (six blocks). In this way, the 6 possible states of the blocks (AABB, ABAB, BBAA, BABA, ABBA, BAAB) will be listed first. And each block will be assigned a number from one to six. Then a number between one and six is randomly selected using the random number table, and then people are selected based on the block

corresponding to the number. will be assigned to the intervention (A) and control (B) groups. This work will continue until the sample volume is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Grape cream and placebo cream will be made by the pharmacist and both grape cream and placebo will be coded (A, B). Two tubes of medicine of the same shape, same color, same texture and weight will be prepared, one tube has an active substance and the other one does not have an effective substance. The research unit and the researcher will not know the type of medicine in the cans of Kedar.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ahvaz-Golestan highway-next to Golestan bazaar-corner of Waliar street-Golestan girls' dormitory complex-Golestan building 2

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Approval date

2023-04-03, 1402/01/14

Ethics committee reference number

IR.AJUMS.REC.1402.022

Health conditions studied

1

Description of health condition studied

Episiotomy wound healing.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Episiotomy healing

Timepoint

in 24 hours after birth, day 7 and 14 after birth

Method of measurement

Based on the Rida system

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: grape seed cream, which will be made in Jundishapur Faculty of Pharmacy of Medical Sciences. To prepare medicine, 35 empty metal tubes of 50 grams with 2% grape seed cream will be prepared and filled with 50 grams of tube from Tolo Gostar Bukhara company/along with an applicator/Using grape seed ointment on the episiotomy wound every night for a week

Category

Treatment - Drugs

2**Description**

Control group: Using placebo on the episiotomy wound every night for a week

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hospitals of the University of Medical Sciences

Full name of responsible person

Fatemeh Razavinia

Street address

Golestan, Ahvaz, Khozestan

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Phone

+98 911 210 3403

Email

fatemehrazavinia15@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Naghmeh Yazdi

Street address

Golestan, Ahvaz, Khuzestan, Iran

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Phone

+98 916 311 9228

Email

naghmehyazdi@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

80

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**

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Razavinia

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Golestan, Ahvaz, Khuzestan, Iran

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Phone

+98 911 210 3403

Email

fatemehrazavinia15@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Razavinia

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Golestan, Ahvaz, Khuzestan, Iran

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Phone

09112103403

Email

fatemehrazavinia15@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Razavinia

Position

Ph. D student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Golestan, Ahvaz, Khuzestan, Iran

City

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Province

Khuzestan

Postal code

6135815751

Phone

+98 911 210 3403

Email

fatemehrazavinia15@gmail.com

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