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

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Iran (Islamic Republic of)

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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

ampling 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 Waliasr street-Golestan girls' dormitory complex-Golestan building 2

City

Ahvaz

Province

Khouzestan

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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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
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
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inquiries

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Person responsible for updating data

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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