Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Investigating the Effect of Rosa damascene and Phenytoin Cream on pain and episiotomy wound healing in primiparous women

Protocol summary

Study aim
Determining and comparison of the average pain score on days 1, 5, 10 after delivery in two intervention groups (Rosa damascene cream and phenytoin cream) and the control group Determining and comparison of the average Reeda score on days 1, 5, 10 after delivery in two intervention groups (Rosa damascene cream and phenytoin cream) and the control group

Design
A triple blinded parallel phase 3 clinical trial study on 120 pregnant women who were divided into 2 intervention groups (Rosa damascene cream and phenytoin cream) and a control group (placebo) with The allocation ratio will be 1:1:1. All three groups will receive routine treatment.

Settings and conduct
Rosa damascene cream and placebo cream based on Vaseline prepared by a traditional medicine pharmacist, as well as phenytoin cream prepared by Amin Pharmaceutical Company at the Traditional Medicine Research Center will be filled in 60 gram white tubes with the same names as A, B and C. and will be provided to the researcher to conduct research. The researcher, the participant, the outcome assessor and the results analyzer (results are coded) and the data safety and monitoring committee will not know the contents of the tubes until the end of the review and the announcement of the results. On the 1th and 5th and 10th days of delivery, pain intensity and improvement of wound healing will be measured by Reeda and VAS questionnaires.

Participants/Inclusion and exclusion criteria
Normal pregnancy and delivery and absence of illness or drug use effective on wound healing

Intervention groups
Intervention group 1: Rosa damascene cream Intervention group 2: Phenytoin cream Control group: placebo cream In all three groups, in addition to routine treatment, from the first day of delivery, every 8 hours for 10 days in the episiotomy area.

Main outcome variables
pain intensity and improvement of wound healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220816055724N1**
Registration date: **2022-09-02, 1401/06/11**
Registration timing: **prospective**

Last update: **2022-09-02, 1401/06/11**
Update count: **0**

Registration date
2022-09-02, 1401/06/11

Registrant information

Name
Fereshteh Farzanazar

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
2022-09-23, 1401/07/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Rosa damascene and Phenytoin Cream on pain and episiotomy wound healing in primiparous women

Public title

The Effect of Rosa damascene and Phenytoin Cream on pain and episiotomy wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Normal pregnancy and delivery Having at least reading and writing literacy perimiparus Age between 15-45 Body mass index (after delivery) between 18.5-30 kilograms per square meter

Exclusion criteria:

Gestational age 37-42 , Cephalic presentation, one alive fetuse suffering from diseases that interfere with wound healing (such as anemia, infection and wounds in the perineum, diabetes, blood pressure, skin, heart, kidney, lung diseases, coagulation disorder, immunodeficiency, hemophilia, disorder connective tissue, depression, malnutrition, mental illnesses, cancer) using drugs effective on wound healing by the mother (anticoagulants, antidepressants, antiepileptics), alcohol, smoking, glucocorticoids, immune system suppressors, antibiotics, and narcotics and psychotropic drugs, not doing The duration of rupture of the Amionitic membran is not more than 18 hours Non-instrumental vaginal delivery with medial and lateral episiotomy incision having a history of previous injury or surgery and visible lesions in the perineum (genital warts, hemorrhoids) and persistent constipation (according to the patient's statement) Spontaneous removal of the placenta

Age

From **15 years** old to **45 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: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

To create a randomization sequence or Random sequence generation, at first, each of the 120 volunteers who meet the criteria for entering the study are given codes from 001 to 120, then using a table of random numbers and choosing the path from top to bottom and keeping in mind Numbers 001 to 040 for the intervention group of rose flower cream or A, numbers 041 to 080 for the intervention group of phenytoin cream or B, and numbers 081 to 120 for the control group or placebo cream or C, the researcher puts his hand on one of the numbers and It moves in the predetermined direction and records the obtained number and assigns it to different groups according to the default type. Then, for the second stage of allocation concealment, three batches of creams are prepared by the traditional medicine doctor in the laboratory in the same shape, color and smell with Vaseline base in each batch in the same 60 gram white tubes and with the name A is prepared for rose cream, B for phenytoin cream and C for placebo cream. In the third stage of randomization or implementation of the process, the participant in the study, the person who created the random sequence, the person who examined the participants in terms of entry and exit criteria and enrolled them in the study, and the person who participated He has allocated the manufacturers to groups, the person who performs the data analysis and the researcher does not know about the allocation of groups and the type of drug in the creams is also known only to the manufacturer, who will not inform others of the results until the end of the analysis.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Rosa damascene cream and placebo cream based on Vaseline prepared by a traditional medicine pharmacist, as well as phenytoin cream prepared by Amin Pharmaceutical Company at the Traditional Medicine Research Center will be filled in 60 gram white tubes with the same names as A, B and C. and will be provided to the researcher to conduct research. The researcher, the participant, the outcome assessor and the results analyzer (the results are coded) and the data safety and monitoring committee will not know the contents of the tubes until the end of the study and the announcement of the results.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Alamlhoda Aenue

City
Arak
Province
Markazi
Postal code
۳۸۱۹۷۹۳۳۶۵
Approval date
2022-06-26, 1401/04/05
Ethics committee reference number
IR.ARAKMU.REC.1401.095

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

2

Description of health condition studied
wound healing
ICD-10 code
O90.1
ICD-10 code description
Disruption of perineal obstetric wound

Primary outcomes

1

Description
episiotomy wound pain
Timepoint
The effect of Rosa damascene cream, phenytoin and placebo on episiotomy pain on days 1, 5 and 10 after delivery (day 1, 5 and 10 after intervention)
Method of measurement
Ruler method- Using the VAS questionnaire

2

Description
Repair of episiotomy wound
Timepoint
The effect of Rosa damascene cream, phenytoin and placebo onepisiotomy wound healing on days 1, 5 and 10 after delivery (day 1, 5 and 10 after intervention)
Method of measurement
Reeda questionnaire

Secondary outcomes

1

Description
Drug side effects
Timepoint
The effect of Rosa damascene cream, phenytoin and placebo on episiotomy Burning on days 1, 5 and 10 after delivery (day 1, 5 and 10 after intervention)
Method of measurement
check list

2

Description
redness
Timepoint
The effect of Rosa damascene cream, phenytoin and placebo on episiotomy redness on days 1, 5 and 10 after delivery (day 1, 5 and 10 after intervention)
Method of measurement
check list

3

Description
wheal
Timepoint
The effect of Rosa damascene cream, phenytoin and placebo on episiotomy wheal on days 1, 5 and 10 after delivery (day 1, 5 and 10 after intervention)
Method of measurement
check list

Intervention groups

1

Description
Intervention group: Rosa damascene cream. cream will be prepared by a traditional medicine pharmacist based on the formulation of Iranian traditional medicine books; In this way, after identifying and ensuring the authenticity of the raw material and some relevant quality factors, the components of the composition are standardized and the samples are controlled from a microbial point of view, and then the relevant cream will be prepared from the extract of this medicinal plant with Vaseline base and inside 60 gram tubes will be poured. These drugs will be prescribed to patients 3 times a day for 10 days.
Category
Treatment - Drugs

2

Description
Intervention group: Phenytoin Cream. The cream is prepared by Amin Pharmaceutical Company and is prepared in the traditional medicine center by a traditional medicine pharmacist in 60 mg white tubes similar to other creams. These drugs will be prescribed 3 times a day for 10 days in the episiotomy area.
Category
Treatment - Drugs

3

Description

Control group: Placebo cream. Vaseline-based cream will be prepared similar to the creams of the intervention group and then will be poured into 60 gram tubes. This medicine will be prescribed 3 times a day for 10 days in the episiotomy area.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Taleghani Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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3848176341
Phone
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research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
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Fatemeh Shabani
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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
It is a privet data

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
-

When the data will become available and for how long
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To whom data/document is available
--

Under which criteria data/document could be used
--

From where data/document is obtainable
--

What processes are involved for a request to access data/document
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Comments
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