Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Investigating the Effect of Arnebia euchchroma and Phenytoin Cream on pain and episiotomy wound healing in primiparous women

Protocol summary

Study aim

Determining and comparing the average pain score and Reeda questionnaire score on days 1, 5, 10 after delivery in two intervention groups (Arnebia euchchroma and phenytoin cream) and the control group.

Design

A clinical trial with a control group with parallel groups, three blind strains, randomized in phase 3 on 120 pregnant women, which is a permutational randomization using numbers in two intervention groups and a control group of 40 people.

Settings and conduct

Creams will be used every 8 hours for 10 days from the first day after delivery. Assessment of pain intensity, improvement of perineum and drug side effects will be done on days 10, 5, after delivery in the women's clinic of Taleghani Arak Hospital. In each examination, standard disposable paper rulers will be used for each participant. Also, at each visit, the checklist of drug side effects is completed. In all 3 groups of routine treatment, the use of 500 mg cephalexin capsules every 6 hours and 250 mg mefenamic acid capsules every 8 hours for one week and washing the wound with normal saline serum. have. The Rida and Pain Questionnaire is used to check the healing rate of episiotomy wound and pain.

Participants/Inclusion and exclusion criteria

Primiparous women between 15 and 45 years of age with normal pregnancy and delivery with middle episiotomy, not using drugs effective in wound healing such as steroids, or suffering from diseases that interfere with wound healing.

Intervention groups

1.Arnebia euchchroma cream consumption intervention group 2. Phenytoin cream use intervention group 3. Control group or use of placebo cream

Main outcome variables

Episiotomy wound pain and healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220816055724N2**
Registration date: **2022-10-18, 1401/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-18, 1401/07/26**
Update count: **0**

Registration date

2022-10-18, 1401/07/26

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 Arnebia euchchroma and Phenytoin Cream on pain and episiotomy wound healing in primiparous women

Public title

The effect of Arnebia euchchroma and Phenytoin Cream on pain and episiotomy wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

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

Exclusion criteria:

Gestational age below 37 weeks or above 42 weeks 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, connective tissue disorder, depression, malnutrition, mental illness, cancer) Taking 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 chemotherapy The duration of rupture of the water bag more than 18 hours Instrumental vaginal delivery with medial or lateral episiotomy incision Non spontaneous removal of the placenta History of injury or previous surgery and visible lesions in the perineum (genital warts, hemorrhoids) and persistent constipation (according to the patient's statement)

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

In this study, with a sample size of 120 people, the participants were randomly placed into three groups of 40 people (two intervention groups and one control group),with using of the block permutation randomization method in order to balance the number of samples allocated in each group. , and with 6 people in each block, we arrange all possible blocks as follows: block 1: BCACAB and BBCACA block 2: and block 3: BCAABC ..... and so on for different sequences. We need 20 blocks for 120 people. We select these blocks from the above permutations using random allocation software, which is capable of generating a random sequence in the block method. For example, if number 1 is the first block and number 3 to be selected as the second block, the people who enter the study will be given BCACAB, BCAABC, in order from left to right, and finally they will be divided into three groups receiving drug A, drug B, and placebo (C).

Blinding (investigator's opinion)

Triple blinded

Blinding description

Creams of three batches are prepared by the traditional medicine doctor in the laboratory in the same shape and color and smell with Vaseline base in each batch in the same 60 gram white tubes and with the names A is prepared for Arnebia euchchroma cream, B for phenytoin cream and C for placebo cream. In the execution 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.

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

Medical Science Of University Of Arak, Sardasht, Mojtamah Payambar Azam, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2022-06-26, 1401/04/05

Ethics committee reference number

IR.ARAKMU.REC.1401.096

Health conditions studied

1

Description of health condition studied
Pain severity
ICD-10 code
G89.28
ICD-10 code description
Other chronic 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
Pain severity
Timepoint
Days 1, 5 and 15 after delivery
Method of measurement
Using the VAS pain questionnaire and Disposable paper ruler

2

Description
Wound healing
Timepoint
Days 1, 5 and 15 after delivery
Method of measurement
Using the Reeda pain questionnaire

Secondary outcomes

1

Description
Drug side effects
Timepoint
Days 1,5,15 after delivery
Method of measurement
Cheek list

Intervention groups

1

Description
Intervention group: Arnebia euchchroma cream is applied every 8 hours on days 1 to 10 after giving birth to the episiotomy wound after washing the perineum.
Category
Treatment - Drugs

2

Description
Intervention group: phnytoeen cream is applied every 8 hours on days 1 to 10 after giving birth to the episiotomy wound after washing the perineum.
Category
Treatment - Drugs

3

Description
Control group: Placebo cream cream is applied every 8 hours on days 1 to 10 after giving birth to the episiotomy wound after washing the perineum.
Category
Placebo

Recruitment centers

1

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

1

Sponsor
Name of organization / entity
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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
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
Arak University of Medical Sciences

Full name of responsible person
Dr Medie Salehi

Position
Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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
-

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
No - There is not 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