

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Investigating the effect of Astragalus fasciculifolius and Phenytoin Cream on pain and episiotomy wound healing in primiparous women

Protocol summary

Study aim

Comparison of the effect of Astragalus fasciculifolius cream and phenytoin cream on pain intensity and healing of episiotomy wound in primiparous women

Design

A randomized triple blind, parallel and phase 3 clinical trial study on 120 primiparous women with use of block permutation randomization method, they divided into 2 intervention groups and a control group with a ratio of 1:1:1.

Settings and conduct

120 volunteer mothers referring to Taleghani Arak maternity hospital with inclusion criteria are randomly divided into three groups (two intervention groups and one control group). Vaseline-based creams prepared by a traditional medicine pharmacist will be filled in similar white tubes (with a capacity of 60 cc) with the names A, B, and C. Researcher, participant, outcome evaluator, and results analyzer (data is coded) and the data safety and monitoring committee will not know the contents of the tubes until the end of the investigation and announcement of the results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal pregnancy and delivery, age 15 to 45 years and body mass index 18 to 30; Exclusion criteria: Suffering from diseases that interfere with wound healing or taking drugs that affect wound healing

Intervention groups

Intervention group 1: Astragalus fasciculifolius creams 10% Intervention group 2: Phenytoin cream 1% Control group: placebo cream All three groups are used their cream in the amount of 5 cc, every 8 hours for 10 days from the first day after delivery, along with routine treatment .

Main outcome variables

Episiotomy wound pain severity and recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220816055724N3**

Registration date: **2022-12-17, 1401/09/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-17, 1401/09/26**

Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

Name

Fereshteh Farzanazar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

farzanazar@yahoo.com

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 Astragalus fasciculifolius and Phenytoin Cream on pain and episiotomy wound healing in primiparous women

Public title

The Effect of Astragalus fasciculifolius and Phenytoin Cream on pain and episiotomy wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

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

Exclusion criteria:

Gestational age below 37 or above 42 weeks Multiple pregnancy Fetus Malpresentation Suffering from diseases that interfere with wound healing such as: anemia, infection and perineum wounds, diabetes, High blood pressure, diseases of skin, heart, kidney, lung, coagulation disorder, immunodeficiency, hemophilia, disorder of connective tissue, depression, malnutrition, mental illnesses, cancer) Using drugs effective on wound healing such as: anticoagulants, antidepressants, antiepileptics), glucocorticoids, immune system suppressors, antibiotics, narcotics and psychotropic drugs, chemotherapy Rupture of Amionitic membran more than 18 hours Instrumental vaginal delivery or non-medial or lateral episiotomy incision Non spontaneous removal of the placenta History of previous injury or surgery or visible lesions in the perineum such as: genital warts, hemorrhoids Alcohol drinking or smoking Persistent constipation (according to the mother 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, to balance the number of samples allocated in each group, the participants will be randomly placed into three groups of 40 people (two intervention groups and one control group) by using the block permutation randomization. We need 20 blocks of 6 for 120 people. We select these blocks using random allocation software, which is capable of generating a random sequence using the

blocking method.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Astragalus fasciculifolius plant cream and placebo cream based on vaseline, prepared by a traditional medicine pharmacist and phenytoin cream prepared by Amin Pharmaceutical Company, at the traditional medicine research center, will be filled in similar white tubes (with a capacity of 60 cc) as named as A, B and C and will be available to the researcher to conduct research. The researcher, the participant, the outcome assessor, the results analyzer and the data safety and monitoring committee will not know the contents of the tubes until the end of the review and announcing 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

Arak University Of Medical Science, Almalhoda Avenue, Arak, Iran

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Approval date

2022-06-26, 1401/04/05

Ethics committee reference number

IR.ARAKMU.REC.1401.097

Health conditions studied

1

Description of health condition studied

Pain severity

ICD-10 code

G89.18

ICD-10 code description

Other acute post procedural pain

2

Description of health condition studied

Wound healing

ICD-10 code

O90.1

ICD-10 code description

Disruption of peritoneal obstetric wound

Primary outcomes**1****Description**

Pain

Timepoint

Days 1, 5 and 10 after delivery

Method of measurement

Visual analog scale (VAS)

2**Description**

Episiotomy wound healing

Timepoint

Days 1, 5 and 10 after delivery

Method of measurement

Reeda Questionnaire

Secondary outcomes**1****Description**

Drug side effect

Timepoint

Days 5 and 10 after delivery

Method of measurement

questionnaire

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

Intervention group 1; Astragalus fasciculifolius Cream 10%: This herbal cream (Astragalus fasciculifolius plant), based on Vaseline and 10% active substance concentration, will be made by a traditional medicine doctor in a traditional medicine laboratory. This cream is applied to the episiotomy area in the amount of 5 cc, every 8 hours, in the first 10 days after delivery. It is performed on the first day by the researcher and then on the following days by the mother (after training the mother). The mother will also receive routine treatment.

Category

Treatment - Drugs

2**Description**

Intervention group 2; Phenytoin Cream 1%: Phenytoin cream 1% is produced by Amin Pharmaceutical Company. It is filled in a 60 mg white tube by a traditional medicine doctor for the purpose of blinding (like the tubes of other groups). This cream is applied to

the episiotomy area in the amount of 5 cc, every 8 hours, in the first 10 days after delivery. It is performed on the first day by the researcher and then on the following days by the mother (after training the mother). The mother will also receive routine treatment.

Category

Treatment - Drugs

3**Description**

Control group: Placebo Cream: The Vaseline cream is filled in a 60 mg white tube by a traditional medicine doctor for the purpose of blinding (like the tubes of other groups). This cream is applied to the episiotomy area in the amount of 5 cc, every 8 hours, in the first 10 days after delivery. It is performed on the first day by the researcher and then on the following days by the mother (after training the mother). The mother will also receive routine treatment.

Category

Placebo

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

Taleghani Maternity Hospital

Full name of responsible person

Dr Abolfazl Safari

Street address

Talegany hospital, Emam khomini Avenue, Arak, Iran

City

Arak

Province

Markazi

Postal code

3816149369

Phone

+98 86 3275 6063

Fax**Email**

It-taleghani@arakmu.ac.ir

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

Arak University of Medical Sciences

Full name of responsible person

Dr Mehdi Salehi

Street address

Arak University of Medical Sciences Complex, Basij Square, Arak, Iran

City

Arak

Province

Markazi

Postal code
3848176341
Phone
+98 86 3417 3532
Fax
+98 86 3383 8319
Email
salehi58@gmail.com

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 Fereshteh Farzanazar
Position
Faculty Member
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Mojtame Paiambarazam, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
38481-7-6341
Phone
+98 86 3417 3520
Fax
+98 86 3417 3521
Email
dr.faezanazar@arakmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person

Dr Mehdi Salehi
Position
Faculty Member
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Mojtame Paiambarazam, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
38481-7-6341
Phone
+98 86 3417 3520
Email
dr.salehi@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Fereshteh Farzanazar
Position
Faculty Member
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Mojtame Paimbarazam, Sardasht , Arak, Iran
City
Arak
Province
Markazi
Postal code
38481-7-6341
Phone
+98 86 3417 3520
Email
dr.farzanazar@arakmu.ac.ir

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
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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

Part of the data is shareable

When the data will become available and for how long

After the end of research

To whom data/document is available

Academic institutions and journals

Under which criteria data/document could be used

Obtaining information about the method and general results

From where data/document is obtainable

Arak University Of Medical Science

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

Written request and during two months

Comments