

# 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

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##### 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

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Talegany hospital, Emam khomini Avenue, Arak, Iran

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

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mehdi Salehi

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

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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  
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Dr Fereshteh Farzanazar  
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## Person responsible for scientific inquiries

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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**  
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**