

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Scrophularia striata plant on episiotomy wound healing in primiparus women

#### Protocol summary

##### Summary

The purpose of this study was to determine the effect of Scrophularia striata plant on episiotomy wound healing in primiparus women. In this three-blind clinical trial study, 80 primiparus women referred to Ganjavian hospital in the city of Dezful were randomly assigned to receive Scrophularia striata plant and placebo (n = 40 in each group, Drugs made from plants and Placebo). Inclusion criteria included Age 18-35years, At least 5 primary education, Age between 37-42 weeks of pregnancy, The fetus with cephalic presentation, 5. Vaginal delivery with episiotomy has a length of 3-4 cm medial side and Exclusion criteria included Body mass less than 18.5 and more than 26, Placental, Curettage in the first 24 hours after birth, Symptoms of infection, Anemia, Anal lesions. The initial dose of Scrophularia striata plant and placebo was administered during 24 hours after delivery. After delivery and episiotomy, Mothers for 10 nights, Once during the night, put medicine on the area episiotomy, So that fully cover the wound and put a sterile gauze on it. Wound healing was measured by REEDA scale (Redness, Edema, Ecchymosis, Discharge, and Adhesive) on 5th, 10th and 21th day after delivery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014111619977N1**

Registration date: **2016-09-18, 1395/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-09-18, 1395/06/28

#### Registrant information

##### Name

Nasibeh Sharifi

##### Name of organization / entity

Department of Midwifery ,Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 918 345 4138

##### Email address

nasibeh.sharifi@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Reproductive Health Research Center School of Nursing and Midwifery Ahvaz University of Medical Sciences

#### Expected recruitment start date

2014-12-22, 1393/10/01

#### Expected recruitment end date

2016-01-30, 1394/11/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Scrophularia striata plant on episiotomy wound healing in primiparus women

#### Public title

Effect of Scrophularia striata plant on episiotomy wound healing in primiparus women

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria included: Age 18-35years, Age between 37-42 weeks of pregnancy, The fetus with cephalic

presentation,, Vaginal delivery with episiotomy has a length of 4-3 cm medial side and Exclusion criteria included: Body mass less than 18.5 and more than 26, Placental, Curettage in the first 24 hours after birth, Symptoms of infection, Anemia, Anal lesions

#### Age

From **18 years** old to **35 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences approved the study design

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan highway, Ahvaz

##### City

Ahvaz

##### Postal code

#### Approval date

2013-05-20, 1392/02/30

#### Ethics committee reference number

Ajums.rec.1392.95

## Health conditions studied

### 1

#### Description of health condition studied

Episiotomy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Primary outcome 1: Redness

#### Timepoint

5th, 10th and 21th day after delivery

#### Method of measurement

Observation and examination ((REEDA) scale)

### 2

#### Description

Primary outcome 2: Edema

#### Timepoint

5th, 10th and 21th day after delivery

#### Method of measurement

Observation and examination ((REEDA) scale)

### 3

#### Description

Primary outcome 3: Ecchymosis

#### Timepoint

5th, 10th and 21th day after delivery

#### Method of measurement

Observation and examination ((REEDA) scale)

### 4

#### Description

Primary outcome 4: Discharge

#### Timepoint

5th, 10th and 21th day after delivery

#### Method of measurement

Observation and examination ((REEDA) scale)

### 5

#### Description

Primary outcome 5: Adhesive

#### Timepoint

5th, 10th and 21th day after delivery

#### Method of measurement

Observation and examination ((REEDA) scale)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Drugs made from *Scrophularia striata* plant. Cream base is containing stearic acid, cetyl alcohol, glycerin, triethanolamine and asprmary. Initial dose was administered within 24 hours after delivery. Mothers for 10 nights, Once during the night, put medicine on the area episiotomy.

#### Category

**2****Description**

Placebo group: Placebo Cream enter the carrier containing the color fits perfectly similar appearance were provided with medication in appropriate circumstances. Initial dose was administered within 24 hours after delivery. Mothers for 10 nights, Once during the night, put medicine on the area episiotomy.

**Category**

Placebo

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

Ganjavian Hospital in Dezful city

**Full name of responsible person****Street address****City**

Dezful

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

Reproductive Health Promotion Research Center,  
Schools of Nursing & Midwifery, Ahvaz Jundishapur Un

**Full name of responsible person**

Ms Poorandokht Afsharifi(Head of the Rrproductive  
Health Promotion Research Center)

**Street address**

School of Nursing & Midwifery, Ahvaz Jundishapur  
University of Medical Sciences; Golestan highway;  
Ahvaz

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Reproductive Health Promotion Research Center, Schools  
of Nursing & Midwifery, Ahvaz Jundishapur Un

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

School of Nursing and Midwifery,Ahvaz Jundishapur  
University of Medical Sciences

**Full name of responsible person**

Shahnaz Najar

**Position**

Instructor, Faculty of Midwifery

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**Full name of responsible person**

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**Position**

Master of Midwifery

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*