Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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 asprmasty. Initial dose was administered within 24 hours after delivery. Mothers for 10 nights, Once during the night, put medicine on the area episiotomy.

Category

Treatment - Drugs

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

Other areas of specialty/work

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Person responsible for scientific inquiries

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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