

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of Aloevera gel on prineal pain & wound healing after episiotomy in primi para women

Protocol summary

Summary

Episiotomy is the most common painful surgeries in women that needs to be repaired. The prevalence of episiotomy in Iran is very high. It has a negative effect on the performance of the first experience of motherhood and relationship between the mother and baby. Delays in repairing increases the risk of infection, limited mobility and sexual dysfunction. For relieving of perineal pain after episiotomy and accelerating of wound healing, various methods have been proposed . The Mucilage in aloe vera leaf tissue, are used for medical purposes. The aim of this study is to evaluate the effect of aloe vera gel on episiotomy pain and wound healing. The participants in this study includes 70 women with singleton pregnancies and full-term nulliparous without any disorder. If anybody have any allergies, trauma and infection will exit from study. The intervention group will receive treatment twice daily for ten days and - Aloe Vera gel is Asans- Barij company- and is expected significant improvement in wound healing and reduce the pain after ten days . Because of the highe prevalence of episiotomy in Iran and it's influence on main activities, author decided to study the effect of Aloevera gel on prineal pain & wound healing after episiotomy in primi para women.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604256888N14**

Registration date: **2016-07-11, 1395/04/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-11, 1395/04/21

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan Universiy of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hamadan university of medical sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Aloevera gel on prineal pain & wound healing after episiotomy in primi para women

Public title

The effect of Aloevera gel on prineal pain & wound healing after episiotomy in primi para women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: primiparus! having single pregnancy, episiotomy without rupture and without using device: gestational age between 37-42 weeks! No history of systemic diseases such as chronic diseases,

cardiovascular disease, respiratory disease, connective tissue coagulation disorders, diabetes, anemia, immune deficiency and ... : The absence of allergy or hypersensitivity (allergic) reactions to topical medication in the past: The lack of underlying disease, eclampsia, and preeclampsia in pregnancy: No rupture of membranes more than 24 hours: lack of prolonged labor: Lack of drug addiction: lack of vulvar and vaginal symptoms of inflammation, a normal BMI: Having mediolateral episiotomy and stitches it with the size of 3-5 cm and separate and cut Goth thread, number zero
Exclusion criteria: not taken properly (Aloe Vera) after delivery: the incidence of allergy (rash, redness and swelling) and infections: incidence of new trauma for any reason at length study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Fahmih Street, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.UMSHA.REC.1395.37

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

O71.4

ICD-10 code description

First degree perineal laceration during delivery

Primary outcomes

1

Description

pain

Timepoint

10 days after delivery

Method of measurement

VAS ruler

2

Description

edema

Timepoint

10 days after delivery

Method of measurement

visual

3

Description

redness

Timepoint

10 days after delivery

Method of measurement

visual

4

Description

Ecchymosis

Timepoint

10 days after delivery

Method of measurement

visual

5

Description

discharge

Timepoint

10 days after delivery

Method of measurement

visual

6

Description

Approximation

Timepoint

10 days after delivery
Method of measurement
visual

7

Description

Sexual function

Timepoint

6 up to 12 weeks after delivery

Method of measurement

FSFI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the intervention group: will be treated with aloe gel-Barij Essence product- twice daily for 10 days.

Category

Treatment - Drugs

2

Description

Group control: will be treated with routine treatment for 10 days.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nazanin Khademi

Street address

Taleghani street

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Ethics Committee of Hamadan University of Medical Sciences

Full name of responsible person

Dr. Bashirian Saeed

Street address

Fahmih Street, Hamadan University of Medical Sciences, Hamadan, Iran

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Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Ethics Committee of Hamadan University of Medical Sciences

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

Hamadan University of Medical sciences

Full name of responsible person

Fatemeh Shobeiri

Position

Ph.D. in Masternal and Child Health

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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