

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of Aloe vera gel on perineal 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 high prevalence of episiotomy in Iran and its influence on main activities, author decided to study the effect of Aloe vera gel on perineal 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 University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1827 6051

##### Email address

shobeiri@umsha.ac.ir

#### 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 Aloe vera gel on perineal pain & wound healing after episiotomy in primi para women

#### Public title

The effect of Aloe vera gel on perineal 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**  
Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan, Iran

**City**  
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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Hamadan  
**Postal code**

## 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*