

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of Aloe vera gel on wound healing after episiotomy

#### Protocol summary

##### Summary

The clinical trial will involve 84 primiparous women admitted for labor and episiotomy in 17 Shahrivar hospital in Saveh, Iran. They are randomly allocated into two groups: intervention (Aloe vera gel twice daily and 2cm of gel for 10 days) and control (receiving the hospital routine betadine sitz bath twice daily for 10 days). An initial assessment will be done for distinction of pain and wound healing level immediately after episiotomy and 4h after episiotomy intervention will start. Pain level and wound healing will be evaluated in 1, 7 and 10 days after episiotomy. The participant's pain will record on VAS and wound healing on REEDA scale (Redness, edema, Echymosis, discharge, Approximation). Researcher will request mother to inform any allergic reaction or infection to researcher for curative action. For blinding, drug administration will be done with researcher and evaluating data will be done with her colleague.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112258517N1**

Registration date: **2012-01-08, 1390/10/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-01-08, 1390/10/18

##### Registrant information

###### Name

Masoumeh Sabzaligol

###### Name of organization / entity

Iran, arak, arak medical university

###### Country

Iran (Islamic Republic of)

##### Phone

+98 25 5234 3395

##### Email address

sabzaligol@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

arak university of medical science and Barij essence co.

##### Expected recruitment start date

2011-12-31, 1390/10/10

##### Expected recruitment end date

2012-03-29, 1391/01/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Aloe vera gel on wound healing after episiotomy

##### Public title

The effect of Aloe vera gel on wound healing after episiotomy

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: nulliparous women with episiotomy without laceration and instrumental delivery; singleton; without systemic chronic disease for example heart and pulmonary diseases, coagulative and connective tissue disease, diabetes, anemia, immune system deficiency, hemophilia, malnutrition, psychological disease, eclampsia, preclampsia, premature rupture of membrane more than 24 hours; prolonged labor and precipitate labor; addiction; vulvovaginitis and hematoma in perineum during 12h after delivery and BMI in range 18 to 21. Exclusion criteria: no cooperation, allergies (rash, redness and edema); infection; new trauma; not coming

for follow-up.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **84**

**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**

Aak University of Medical Sciences

**Street address**

Medical pardis, Basij Sq, Sardasht, Arak, Iran

**City**

Arak

**Postal code****Approval date**

2011-10-17, 1390/07/25

**Ethics committee reference number**

12-114-90

**Health conditions studied****1****Description of health condition studied**

Episiotomy

**ICD-10 code**

O71.9

**ICD-10 code description**

Obstetric trauma, unspecified

**Primary outcomes****1****Description**

Pain severity

**Timepoint**

At days 1, 7 and 10

**Method of measurement**

VAS scale

**Secondary outcomes****1****Description**

Wound healing

**Timepoint**

At days 1, 7 and 10

**Method of measurement**

Reeda scale

**Intervention groups****1****Description**

Intervention group will receive aloe vera gel (twice daily and 2cm of gel for 10 days). A initial assessment will be do for distinction of pain and wound healing level immediate after episiotomy and 4h after episiotomy intervention will do. pain level and wound healing will assess in day 1,7 and 10.

**Category**

Treatment - Drugs

**2****Description**

In control group routine care is betadine sitz bath twice a day (for 10 days). A initial assessment will be do for distinction of pain and wound healing level immediate after episiotomy and 4h after episiotomy intervention will do. pain level and wound healing will assess in day 1,7 and 10.

**Category**

Treatment - Drugs

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

Saveh's 17 shahrivar hospital

**Full name of responsible person**

Masoume Sabzaligol

**Street address**

Koshesh panah, Kaveh industrial city, Saveh

**City**

Saveh

**Sponsors / Funding sources****1****Sponsor**

**Name of organization / entity**

Arak university of medical science

**Full name of responsible person**

Saeed changizi ashtiani

**Street address**

medical pardis,Basij Sq,Sardasht,arak

**City**

Arak

**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 science

**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**

Arak University of Medical Science

**Full name of responsible person**

Masoumeh Sabzaligol

**Position**

Ms

**Other areas of specialty/work****Street address**

Koshesh panah, Kaveh industrial city, Saveh

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+98 25 5234 3395

**Fax****Email**

sabzaligol@arakmu.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Masoumeh Sabzaligol

**Position**

Faculty of Nursing

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Masoumeh Sabzaligol

**Position**

MSc

**Other areas of specialty/work****Street address****City**

Saveh

**Postal code****Phone**

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**Fax****Email****Web page address****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*