

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

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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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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**

koshesh panah, kaveh industrial city, Saveh

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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**

+98 25 5234 3395

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*