Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of topical effect of aloe vera gel and lavender essential oil in faster healing and reduction of episiotomy inflammation in patients referred to Hajar Hospital in Shahrekord

Protocol summary

Study aim

Comparison of topical effect of Aloe-vera gel and lavender essential oil in faster healing and reduction of episiotomy inflammation in patients referred to Hajar Hospital in Shahrekord

Design

Double-blind, randomized phase 3 clinical trial on 195 patients. A table of random numbers is used for randomization.

Settings and conduct

A double-blind study in which researchers and participants are unaware of the drug used on women referred to Hajar Hospital in Shahrekord. Patients are randomly divided into 3 groups: control group receiving routine care (lubricant gel) for 10 days The first group of routine care + aloe vera gel (2 cm from the gel inside the tube) episiotomized for 10 days The second group of routine care + 5% lavender essential oil gel for 10 days Finally, the extent of inflammation and infection of the episiotomy wound is examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria included age 18 to 35 years, BMI 19.8 to 26 kg / m2, gestational age 37-42 weeks, infant weight between 2500 to 4000 g, singleton pregnancy, primiparous, no specific disease (cardiovascular disease) , Liver, kidney, diabetes, immunodeficiency, depression), no smoking, alcohol and drugs, no long-term rupture of the membrain> 18 hours. Exclusion criteria include hematoma, infection, obstruction of labor (prolongation of labor and dystocia), need for resuscitation, extended episiotomy, heavy postpartum hemorrhage, vacuum use, postpartum perineal manipulation, allergy to aloe vera or lavender

Intervention groups

Control group receiving routine care (lubricant gel) for 10 days The first group of routine care + aloe vera gel (2 cm from the gel inside the tube) episiotomized for 10 days The second group of routine care + 5% lavender essential oil gel for 10 days

Main outcome variables

Inflammation and infection of the episiotomy wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210607051509N1**
Registration date: **2021-11-21, 1400/08/30**
Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**
Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

zahra abedi koupaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3335 1044

Email address

st-abedikoupaee.z@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of topical effect of aloe vera gel and lavender essential oil in faster healing and reduction of episiotomy inflammation in patients referred to Hajar Hospital in Shahrekord

Public title

Comparison of Aloe-vera gel and lavender essential oil on inflammation of episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body mass index 19.8 to 26 kg per square meter Gestational age 37-42 weeks Baby weight between 2500 and 4000 grams Single pregnancy Primi-para No specific disease (cardiovascular disease, liver, kidney, diabetes, immunodeficiency, depression) No smoking, alcohol and drugs No long-term rupture of the membrain for more than 18 hours

Exclusion criteria:

Hematoma, Infection, Disorders of labor (prolongation of labor and vestibule), Neonatal resuscitation, Episiotomy, Excessive postpartum hemorrhage, Vacuum use, Postpartum perineal manipulation, Aloe-vera or lavender allergy

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **195**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is divided using code 1 and code 2 cards and selected by the patient. And the rest enter in groups one by one.

Blinding (investigator's opinion)

Double blinded

Blinding description

The tube is packaged and coded by a pharmacist colleague. The patient and the researcher are unaware of its contents.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Parastar Aven.Hajar Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2021-06-23, 1400/04/02

Ethics committee reference number

IR.SKUMS.REC.1400.081

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

O71

ICD-10 code description

Other obstetric trauma

Primary outcomes

1

Description

Infection rate

Timepoint

The third, seventh and tenth day

Method of measurement

REEDA scale

Secondary outcomes

1

Description

Inflammation rate

Timepoint

Day 3- 7 -10

Method of measurement

Iran Phlebitis Checklist

Intervention groups

1

Description
Control group: Patients receiving routine care (receiving lubricant gel) daily for up to 10 days
Category
Treatment - Drugs

2

Description
Intervention group 1: Routine care + aloe vera gel (2 cm from the gel inside the tube) episiotomized for 10 days
Category
Treatment - Drugs

3

Description
Intervention group 2: Routine care + 5% lavender essential oil gel daily for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital, Shahrekord
Full name of responsible person
Lobat Jafarzade
Street address
Parastar Aven
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Phone
+98 38 3222 0016
Email
shivaabedik@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghy
Street address
Parastar Aven
City
Shahrekord
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Chahar-Mahal-va-Bakhtiari
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8816754633
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Email
shivaabedik@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Zahra Abedi Koupaee
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long
2022-2023

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
I have not decided yet

From where data/document is obtainable
I have not decided yet

What processes are involved for a request to access data/document
I have not decided yet

Comments