

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of teueriumpolium and aloe vera gel on episiotomy wound healing in primiparous women

Protocol summary

Study aim

Evaluation of effect of teueriumpolium and aloe vera gel on episiotomy wound healing

Design

This is a one blinded randomized clinical trial, in which at least 50 eligible patients will be randomly assigned to the intervention and control groups.

Settings and conduct

The eligible women who delivered and will refer to Khalijfars Hospital, Bandar-abbas during the study period will be enrolled in the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years; Gestational age of 35 weeks or higher; Medio lateral incision and 2nd degree episiotomy; Normal body mass index; Primiparous
Exclusion criteria: Cigarette smoking; Condiloma lesions or herpes in perineum; Preeclampsia; Diabetes; Coagulopathy; Cardiovascular diseases; Renal failure

Intervention groups

Intervention group: Teueriumpolium and aloe vera gel twice on location of episiotomy wound for 10 days
Control group: Placebo gel twice on location of episiotomy wound for 10 days

Main outcome variables

Primary outcome: Episiotomy wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N9**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Fatemeh Bazarganipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 76 3366 6367

Email address

bazarganipour@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-20, 1399/07/29

Expected recruitment end date

2020-12-19, 1399/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of teueriumpolium and aloe vera gel on episiotomy wound healing in primiparous women

Public title

Teueriumpolium and aloe vera gel on episiotomy wound

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 35 years Gestational age 37 weeks and above Medio lateral incision and 2nd degree episiotomy
Normal body mass index Primiparous

Exclusion criteria:
Cigarette smoking
Condiloma lesions or herpes in perinea
Preeclampsia
Diabetes
Coagulopathy
Cardiovascular diseases
Renal failure

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

Gender
Female

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple. The random allocation sequence will be determined using the "computer Random generation" computer program. The sealed envelopes encoded and non-transparent (A and B) for the allocation of subjects to intervention (A) and control (B) groups will be used.

Blinding (investigator's opinion)
Single blinded

Blinding description
The one-way blindness of this study means that the patient did not know the type of treatment prescribed and the shape, size, and color of the gel in the intervention group were similar to the control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences

Street address
Vice chancellor of research, Shahid Mohamadi Hospital, Bandarabbas, Hormozgan

City
Bandarabbas

Province
Hormozgan

Postal code
7916839319

Approval date
2020-10-19, 1399/07/28

Ethics committee reference number

IR.HUMS.REC.1399.371

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

O90.1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes

1

Description

Episiotomy wound healing

Timepoint

5 and 10 days after intervention

Method of measurement

REEDA questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Teueriumpolium and aloe vera gel twice on location of episiotomy wound for 10 days. Each 30 grams of gel contains 6% of teueriumpolium extract and 15% of aloe vera extract. This gel is made in the laboratory of Yasuj Medicinal Plants Research Center, Iran.

Category

Treatment - Drugs

2

Description

Control group: Placebo gel twice on location of episiotomy wound for 10 days. This gel is made in the laboratory of Yasuj Medicinal Plants Research Center, Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandare-abbas University of Medical Sciences

Full name of responsible person

Maryam Azizi

Street address

Shahid Mohamadi Hospital, Bandarabbas, Hormozgan

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maryamazizikut86@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teymoor Aghamolaei

Street address

Vice chancellor of research, Shahid Mohamadi Hospital, Bandarabbas, Hormozgan

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Maryam Azizi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available