

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the efficacy of Teucrium polium ointment and placebo in the treatment of episiotomy ulcers in primiparous women.

Protocol summary

Study aim

1. Determination and comparison of swelling, redness, secretion, bruising and opening of episiotomy site before intervention and in the first 24 hours after delivery and on days 5 and 10 postpartum in Colpore ointment group
2. Determination and comparison of episiotomy healing before and during the first 24 hours of delivery and 5 and 10 days postpartum in the Colpore and placebo ointment group.
3. Determine the side effects of consuming Colporea ointment
4. Determination of satisfaction with treatment in Colpore ointment group

Design

A clinical trial with control group, with parallel groups, triple blind, randomization using random allocation software. The sample size is 90 people.

Settings and conduct

The study will be conducted as triple blind in which the researcher, the patient and statistician are unaware of the drugs' contents. Sampling places will be Shahid Beheshti hospital in Isfahan .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous women giving birth; Ages 18 to 35 years; Gestational age between 37 and 42 weeks; Having single fetal cephalic presentation.
Inclusion criteria: Allergy to Colpore ointment; Not using ointment regularly; infant hospitalization in intensive care unit; Having sex in the first 10 days after delivery.

Intervention groups

Intervention group: Colporea 2% ointment is applied once daily, Two centimeters (cm), for 10 days on episiotomy ulcer. Initial assessment of wound healing is done 24 hours after the intervention and then on the 5th and 10th days. Control group: Placebo ointment once daily, 2 cm, is applied on episiotomy ulcer for 10 days. Initial assessment of wound healing is done 24 hours after the intervention and then on the fifth and tenth days.

Main outcome variables

Bruising, edema, opening, secretion and redness of

episiotomy ulcer.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100130003226N18**

Registration date: **2019-11-11, 1398/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-11, 1398/08/20**

Update count: **0**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name

Mahrokh Dolatian

Name of organization / entity

Shahid Beheshti University of Medical Scenices

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-21, 1398/05/30

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Teucrium polium ointment and placebo in the treatment of episiotomy ulcers in primiparous women.

Public title

The effect of Colporea ointment in the treatment of episiotomy wounds.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women aged 18 to 35 years Primiparous
Gestational age between 37 to 42 weeks Having a single fetus with cephalic presentation Fetal weight between 2500 and 4000 g BMI between 18.5 and 25 Vaginal delivery with intermediate episiotomy without rupture (grade II) Normal first, second and third stage of the delivery

Exclusion criteria:

Amniotic sac rupture more than 24 hours Allergy to Colpore Ointment Having fever, sinus infection and hematoma Infant hospitalization at intensive care unit Having postpartum hemorrhoids or fissures Having sex in the first ten days after delivery

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Available (simple) and goal-based. In this way, all patients who are eligible for the study will be screened. The delivery of the medicine to the patients is in a box containing a number of cards that are evenly written in the English alphabet "A and B" with the placebo oint code and Teucrium polium (Researcher Unaware of the contents of the worms) we match, and patients choose a card at random. And they deliver the medicine on the letters.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is triple-blind randomized controlled clinical trial. At the diagnostic stage of the demographic and midwifery and delivery questionnaire the patient's name is not written. At the stage of giving the patient a placebo

ointment or Teucrium Polium are marked with the English letter A and B, coded by the pharmacist. The researcher is not aware of its contents and the patient also randomly selects one of the placebo ointment or Teucrium Polium. At the referral stage after treatment and the statistics professor is also unaware of the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

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6th floor, Building no.2 SBMUS, Parvaneh str., Yemeni Ave. Shahid Chamran Highway

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Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.055

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

Episiotomy

ICD-10 code

obstetric

ICD-10 code description

071.9

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

Episiotomy wound healing

Timepoint

Before the intervention, 24 hours, 5 and 10 days after treatment

Method of measurement

REEDA scale assess 5 items such as Redness, Edema, Ecchymoses, Wound secretion, and Wound dehiscence.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Uses 2% Colpore ointment for 10 days (daily) at a rate of two centimeters, on episiotomy wound. This ointment is produced at the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences. Initial assessment of wound healing is done 24 hours after the intervention and then on the fifth and tenth days.

Category

Treatment - Drugs

2

Description

Control group: Use placebo ointment (quite similar to Calpore ointment) for 2 days (daily) at 2 cm, on episiotomy ulcer. This ointment is produced at the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences. Initial assessment of wound healing is done 24 hours after the intervention and then on the fifth and tenth days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Atena Mohammady Rouzbahani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Shahid Beheshti 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

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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
Shahid Beheshti 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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