

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of cinnamon (*Cinnamomum zelanicum*) on healing and pain of episiotomy among primigravid women: A Randomized Controlled Trial

Protocol summary

Summary

The aim of this study is to determine the effect of Cinnamon ointment on healing and pain from episiotomy wounds in women. In this triple blind clinical trial, 144 eligible women will be allocated into two, Cinnamon or placebo ointment, groups using block randomization with allocation ratio 1:1 and block sizes of 4 and 6 determined with a computerized program. The ointments will be produced by the pharmacist colleague in similar color and will be put into similar tubes with no label. A person not involved in sampling and data collection will put the ointment tubes into sequentially numbered sealed opaque envelopes to conceal allocation sequence. After filling in baseline characteristics and measuring the episiotomy incision length, participants will sequentially get the envelopes and will be asked to use one finger of the ointment every 12 hours. The wound pain will be assessed using visual analogue scale (VAS) one hour after finishing episiotomy repair (before any intervention), 4 ± 1 hours after using the ointments. Also at 8 ± 1 hours after using the ointments and on the tenth day postpartum visit, the pain and healing (using REEDA scale in lithotomy position) will be assessed. In SPSS-ver. 13, ANCOVA will be used to compare post-intervention mean pain scores between the groups controlling the pre-intervention pain scores and student's-t to compare the repair scores.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211303706N18**
Registration date: **2012-12-13, 1391/09/23**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-13, 1391/09/23

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cinnamon (*Cinnamomum zelanicum*) on healing and pain of episiotomy among primigravid women: A Randomized Controlled Trial

Public title

The effect of cinnamon (*Cinnamomum zelanicum*) on healing and pain of episiotomy among primigravid women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: • being primipara • being literate • Access to telephone line • gestational age 37 to 42 weeks • Having a singleton live child • aged 20 to 35 years • Repair of Episiotomy incision by a provider with at least six months experience • willingness to participate in the study. • willingness and ability to continue coming to Alzahra or Taleghani hospital for the care Exclusion criteria: • use of drugs or psychotropic substances (according to the woman or her physical records) • use of certain drugs (according to the participant) • history of diseases like systemic disease, cardiac, renal, pulmonary, coagulation disorders, immune deficiency, connective tissue disorders, diabetes, mental illness, haemophilia that may intervene with the healing • following a special diet • long-term rupture of amniotic sac (over 18 hours) • severe anaemia (haemoglobin less than 7) (based on haemoglobin assessed at admission) • history of hypersensitivity to certain drugs • extension of episiotomy (tears of grade 3 or 4) • operative delivery

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research deputy, Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

Approval date

2012-12-03, 1391/09/13

Ethics committee reference number

91157

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

Severity of episiotomy pain

Timepoint

Before intervention and 4 ± 1 , 8 ± 1 hours after intervention and ten days after intervention

Method of measurement

Visual analogue scale (VAS)

2

Description

Episiotomy healing wound

Timepoint

Pre intervention and 8 ± 1 hour after intervention and ten days after delivery

Method of measurement

REEDA (Redness, Edema, Ecchymosis, Discharge, Approximation)

Secondary outcomes

1

Description

Number of Mefenamic acid capsules used

Timepoint

Tenth day after delivery

Method of measurement

count of remaining Capsules

Intervention groups

1

Description

Intervention group: Receiving cinnamon ointment

Category

Treatment - Drugs

2

Description

Control group: Receiving placebo ointment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mohammadi Azam

Street address**City**

Tabriz

2

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Mohammadi Azam

Street address**City**

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz university of medical sciences

Full name of responsible person

Dr. Kazem Shakouri

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Golgasht st.

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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

Research deputy of Tabriz university of medical sciences

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**

Faculty of Nursing and Midwifery, Tabriz University of

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Full name of responsible person

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Position

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Position

Assistant professor, PhD in Reproductive Health

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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