Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 envelops 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

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Name of organization / entity

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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
Befor 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 afer delivery

Method of measurement
REEDA (Redness, Edema, Ecchymosis, Discharge, Approximation

Secondary outcomes

1

Description
İNumber 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
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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
Street address
Golgasht st.
City
Tabriz
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
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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