Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Zingiber officinale on healing and pain of episiotomy among primigravida women: A Randomized Controlled Trial

Protocol summary

Study aim

Comparison of the mean episiotomy pain score.
Comparison of the mean of episiotomic repair score.

Design

This research is a randomized controlled trial, triple blind. With a sample of 70 people. Allocation of samples with an allocation ratio of 1: 1 will have a control group by random blocking method (blocks 4 and 6).

Settings and conduct

It is possible to conduct research in Al-Zahra Hospital in Tabriz. Eligible people and volunteers are randomly divided into two groups, one group will be given ginger extract ointment and the other group will be given placebo. Participants, researchers, data collectors and analysts are blind.

Participants/Inclusion and exclusion criteria

Primiparous women; lack of drug and psychotropic; age range 35-18 years old; live birth; single fetus; do not use any special medicine; failure to follow the special diet; no anemia during pregnancy; lack of early PPH; no history of prenatal vaginal examinations and manipulations; extent or large episiotomy (repair length 4-3 cm); willingness and possibility for the mother to visit Al-Zahra Hospital on days 5 and 15; no history of reconstructive surgery on the vagina and intercostals; lack of long-term rupture of the amniotic sac; do not use blood pressure medications; do not use topical lidocaine cream; do not use mopericin; do not use curettage in mothers.

Intervention groups

One group will be given ginger extract ointment and the other will be given placebo. The extent of wound healing by REEDA scale will be evaluated by the researcher before discharge and 1.5 ± 1.5 and 1 day after the intervention. The average severity of pain and discomfort at the site of the episiotomy incision in each group before discharge will be assessed by the VAS Pain Visual Assessment Scale.

Main outcome variables

Pain score and repair score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110922007618N9**
Registration date: **2020-08-14, 1399/05/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-14, 1399/05/24**
Update count: **0**

Registration date

2020-08-14, 1399/05/24

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-21, 1399/04/31

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Zingiber officinale on healing and pain of episiotomy among primigravida women: A Randomized Controlled Trial

Public title
The effect of Zingiber officinale on healing and pain of episiotomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Primiparous women The lack of drug and psychotropic Age range 35-18 years Birth of a live, single fetus Do not use any special medicine(such as anti-inflammatory drugs other than acetaminophen and coagulation based on the patient's statements) history of impaired wound healing disease, like systemic disease, cardiac, renal, pulmonary, coagulation disorders, immune deficiency, connective tissue disorders, diabetes,haemophilia Failure to follow the special diet No anemia during pregnancy The lack of early PPH No history of prenatal vaginal examinations and manipulations extent or large episiotomy (repair length 4-3 cm) Willingness and possibility for the mother to visit Al-Zahra Hospital on days 5 and 10 No history of reconstructive surgery on the vagina and intercostals (according to the woman) Lack of long-term rupture of the amniotic sac (more than 18 hours) Do not use blood pressure medications (mothers with high blood pressure and preeclampsia) Do not use topical lidocaine cream Do not use mopericin Do not use curettage in mothers

Exclusion criteria:
Unwillingness to participate in the study

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible individuals and volunteers are randomly divided into blocks (4 and 6 blocks) with a 1: 1 allocation ratio randomly divided into two groups: one group of ginger extract ointment (intervention group) and the other group of placebo (Control group) will be given. The amount of pain is measured with a visual pain measuring instrument and the mean wound condition score is measured by the REEDA scale. The package will be numbered in order.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The placebo will be prepared in the form of sterile ointment and in closed tubes of both shape and color with drug packages. In addition to the person who determines the order of the individuals in the groups, the only person who will know the type of drug prescribed will be the researcher's assistant, and the participants, the researcher, the data collection and analyzer will not be informed.

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 St. - Tabriz University of Medical Sciences - Central Building No. 2 Floor 3 - Research Deputy

City
Tabriz

Province
East Azarbaijan

Postal code
5138947-977

Approval date
2020-06-30, 1399/04/10

Ethics committee reference number
IR.TBZMED.REC.1399.333

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
Before intervention,12 hours after delivery and on days 5 and 15

Method of measurement
Epidatomic wound healing scale; REEDA (Redness, Edema, Ecchymosis, Discharge, Approximation)

2

Description
The severity of episiotomy pain
Timepoint
Before intervention,12 hours after delivery and 5 and 15 days later
Method of measurement
Visual Pain Scale (vas)

Secondary outcomes

1

Description
Count the acetaminophen pills used
Timepoint
Fifteenth day after delivery
Method of measurement
Counting tablets

2

Description
The frequency of side effects in the group receiving ginger extract ointment ginger and placebo
Timepoint
Fifteenth day after delivery
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Receive ginger extract ointment to apply the ointment to the incision every 12 hours for 10 days.
Category
Treatment - Drugs

2

Description
Control group: Apply the placebo ointment to the ointment every 12 hours for 10 days on the incision site.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Fatemeh Cheshfar
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Tabriz School of Nursing and Midwifery, Shahnaz St.
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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
Tabriz 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
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Full name of responsible person
Fatemeh Cheshfar

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
The results of the clinical study will be published in the form of an article.
When the data will become available and for how long
Immediately after printing the results.
To whom data/document is available
All researchers.
Under which criteria data/document could be used
Scientific use with reference to the article.
From where data/document is obtainable
Email Dr. Soheila Bani : banis@tbzmed.ac.ir
What processes are involved for a request to access data/document
Maximum week after correspondence via email.
Comments