

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Soheila Bani

Name of organization / entity

Tabriz University of Medical Sciences

Country

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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

Street address

Tabriz School of Nursing and Midwifery, Shahnaz St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

Research Deputy, 3rd floor, Central Building No.2, Tabriz University of Medical Sciences, 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

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

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Cheshfar

Position

Master of Midwifery Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Soheila Bani

Position

Faculty

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Cheshfar

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