Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Nigella sativa oil on pain and healing of episiotomy: a three-Blind randomized controlled trial

Protocol summary

Study aim
To determine the effect of Nigella sativa gel on pain and wound healing due to episiotomy

Design
Clinical trial with a control group, with parallel groups, triple blinded, randomized with blocking method, phase three on 60 patients. The randomizer software will be used for randomization.

Settings and conduct
This study will be performed in Dr. Mahzad Educational-Medical Center of Urmia. Nigella sativa gel will be used daily at the episiotomy site without massage for a week. Wound healing rate will be assessed by RIDA scale before discharge and 10±1 days after intervention. The mean pain intensity will be assessed before discharge and again on day 10±1 after the intervention by the Visual Pain Scale (VAS).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Live and single fetus delivery; Following a special diet; Willingness and possibility of the mother to visit the comprehensive women's center of Dr. Mahzad in Urmia on the 10th day. Exclusion criteria: Using of specific medications (such as anti-inflammatory and anticoagulants); History of diseases that impair wound healing such as systemic, heart, kidney, lung, coagulation disorders, immunodeficiency, connective tissue disorders, diabetes, anemia, mental illness, hemophilia; Having severe anemia during pregnancy; Early bleeding after delivery; History of vaginal examinations and manipulations before delivery; Large or enlarged episiotomy; Long-term rupture of the amniotic sac (more than 18 hours); Addiction to drug and psychotropic substances.

Intervention groups
The intervention group 1 or treatment group: This group will receive Nigella sativa gel daily at the episiotomy site without massage for a week; The intervention group 2 or control group: This group will receive placebo gel daily at the episiotomy site without massage for a week.

Main outcome variables
Wound healing and pain severity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120718010324N68**
Registration date: **2022-02-06, 1400/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-06, 1400/11/17**
Update count: **0**

Registration date
2022-02-06, 1400/11/17

Registrant information
Name
Mojgan Mirghafourvand
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-29, 1400/11/09
Expected recruitment end date
2022-07-31, 1401/05/09
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nigella sativa oil on pain and healing of episiotomy: a three-Blind randomized controlled trial

Public title

The effect of Nigella sativa oil on pain and healing of episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Delivery of a live and single fetus Not following a special diet (according to the woman) Willingness and possibility of the mother to visit the comprehensive women's center of Dr. Mahzad in Urmia on the 10th day

Exclusion criteria:

Long-term rupture of the amniotic sac (more than 18 hours) Large or enlarged episiotomy History of pre-delivery vaginal examinations and manipulations Early vaginal bleeding after delivery Having severe anemia during pregnancy History of diseases that interfere with wound healing such as systemic, heart, kidney, lung, coagulation disorders, immunodeficiency, connective tissue disorders, diabetes, anemia, mental illness, hemophilia Using of specific medications (such as anti-inflammatory drugs and anticoagulants based on the patient's statements) Addiction to addictive and psychotropic substances (based on the woman's statements and case file)

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will be assigned to two groups (one group receiving Nigella Sativa gel and one group receiving placebo gel with the same protocol) by block randomization method with block sizes of 4 and 6 and a allocation ratio of 1: 1. To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer software, and the Nigella Sativa gel and placebo gel will be placed in the same packages numbered sequentially.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants, researcher and data analyst will be blinded in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.TBZMED.REC.1400.838

Health conditions studied

1

Description of health condition studied

Episiotomy wound healing

ICD-10 code

O90.1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes

1

Description

Wound healing score

Timepoint

Before discharge and 10±1 days after intervention

Method of measurement

REEDA scale

Secondary outcomes

1

Description
Pain score
Timepoint
Before discharge and 10 ± 1 days after intervention
Method of measurement
Visual Analog Scale

Intervention groups

1

Description
Intervention group or treatment group: Black seed gel with a concentration of 15% will be prepared by the pharmacy department of Tabriz University of Medical Sciences in the laboratory of the Pharmacy School and it will be used by the participants three times a day in the amount of one fingertip at the episiotomy site without massage for a week.
Category
Treatment - Drugs

2

Description
Control group: Placebo of black seed gel (paraffin) with a concentration of 15% will be prepared by the pharmacy department of Tabriz University of Medical Sciences in the laboratory of the Pharmacy School and it will be used by the participants three times a day in the amount of one fingertip at the episiotomy site without massage for a week.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Comprehensive Women's Hospital
Full name of responsible person
Afsaneh Alizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Parviz Shahabi
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South Shariati Street
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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
Afsaneh Alizadeh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available