Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation the effect of of ostrich oil on pain intensity and episiotomy wound healing in primiparous women

Protocol summary

Study aim
Determining the effect of ostrich oil on pain intensity and episiotomy wound healing in primiparous women referred to Mahdiyeh Hospital in Tehran

Design
A clinical trial with a control group, with parallel groups, three blinded, randomized, phase 3 on 112 patients, rand function of Excel software was used for randomization.

Settings and conduct
Post-partum Department and Women's Clinic of Mahdieh Hospital, Tehran, triple-blind (mother, researcher and statistician)

Participants/Inclusion and exclusion criteria
Inclusion criteria: Primiparous 18 to 35 years literate A resident of Tehran Mother's body mass index in the range of 18.5 to 25 at the beginning of pregnancy Gestational age 37 to 42 full weeks Live singleton fetus with cephalic presentation The baby weighs between 2500 and 4000 gr Vaginal delivery with mid-lateral episiotomy and without assisting tools 1st and 2nd grade episiotomy No smoking, alcohol and drugs Free of any underlying disease that interferes with wound healing and obstetric problems Not taking medicine effective on wound healing No rupture of the membrane for more than 24 hours Absence of severe anemia No disturbance in the progress of labor and prolonged labor No history of allergy to topical drugs No history or current mental illness Non-entry criteria: Hematoma Puerperal infection Postpartum hemorrhage Hospitalization of the baby Sex in the first 10 days Placental curettage

Intervention groups
Intervention group: After obtaining informed consent, the participants will be given a 30-gram tube of ostrich oil to apply 2 cm every 12 hours in the area of the suture for ten days after delivery. Control group: after obtaining informed consent, the participants will be given a 30 gram tube of Eucerin oil to use in the area of the suture at the rate of 2 cm every 12 hours for ten days after delivery.

Main outcome variables
Pain intensity Episiotomy wound healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231007059638N1**
Registration date: **2024-01-28, 1402/11/08**
Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**
Update count: **0**

Registration date
2024-01-28, 1402/11/08

Registrant information

Name
Seyede Zahra Mousavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-09, 1402/11/20

Expected recruitment end date
2024-04-18, 1403/01/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of of ostrich oil on pain intensity and episiotomy wound healing in primiparous women

Public title

Evaluation the effect of of ostrich oil on pain intensity and episiotomy wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The mother to be primiparous. Be in 18 to 35 age range. Be literate in reading and writing. Be a resident of Tehran. Be Iranian. Mother's Body Mass Index(BMI) be in 18.5 to 25 range in the beginning of pregnancy. Gestational age be 37 to 42 full weeks. Fetus be live singleton with cephalic presentation. Neonatal weight be 2500 to 4000 gr. Vaginal delivery with mediolateral episiotomy and without assisting tools(forceps, vacuum). Be 1 and 2 grade episiotomy. Do not consume cigarettes, alcohol or drugs. The episiotomy incision site be repaired by chromic cut-coat thread. free of any underlying disease that interferes with wound healing (chronic systemic, cardiopulmonary, connective tissue diseases, anemia, diabetes, malnutrition, hemophilia, mental disorders, and kidney failure) and obstetric problems such as diabetes in pregnancy, preeclampsia, eclampsia, coagulation disorders, Decollement, chorioamnionitis and immune system defects according to the person's statements and the medical/midwifery record. She has not used any drugs effective on wound healing, such as corticosteroids, anticoagulants, antiepileptics, immunosuppressants, broad-spectrum antibiotics, and chemotherapy. Rupture of membrane should not last more than 24 hours. Do not have severe anemia during pregnancy (hemoglobin less than 7). Disruption in the progress of labor and prolongation of the stages of labor (the duration of the first stage of labor more than 14 hours, the duration of the second stage more than 2 hours and the duration of the third stage more than half an hour) have not occurred. There is no history of allergy to topical and herbal medicines according to the person's statement. Don't have family conflicts and severe financial problems in the last 1 month. Don't have any history or current illness of mental disorders such as depression according to the mother's statement.

Exclusion criteria:

The person does not want to continue participating in the research. On the designated days (the fifth day and the tenth day) after delivery, he has not returned for care. Allergic to ostrich oil. He has not used the oil regularly and for more than 2 times. Having a hematoma at the episiotomy site in the first 24 hours after delivery. Having fever and puerperal infection. Having abnormal bleeding in the first 24 hours after delivery. Having severe constipation after delivery and during the study. Having hemorrhoids or anal fissure after childbirth. The baby was hospitalized during the study. Have sex in the first 10 days after giving birth. If the samples need placenta curettage.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

The function of random numbers is used to randomize and assign people to groups. The samples will be randomly entered into two intervention and control groups by three-blind random allocation method using Excel software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this intervention, the researcher, the statistical analyst and the participants (primiparous mothers) are kept blind to the allocation of the study groups (triple-blind). In this way, the oils will be prepared and coded by the doctor of pharmacology in the same shape, color and smell, the researcher will not know the nature of the package and will receive the packages. After obtaining informed consent from the samples and explaining the research to them, the packages will be provided to the samples. After collecting the data, the statistical analyst is also unaware of which group (control or intervention) each of the samples is in.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Valiasr

City

Tehran

Province

Tehran

Postal code
1983969411
Approval date
2024-02-09, 1402/11/20
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.196

Health conditions studied

1

Description of health condition studied
Episiotomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Wound healing score
Timepoint
1st, 5th and 10th day after delivery
Method of measurement
Perineal healing control form (REEDA)

2

Description
Maternal pain intensity score
Timepoint
1st, 5th and 10th day after delivery
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention group: Ostrich oil will be prepared in 30 gram oil tubes containing ostrich oil to be used twice a day for two centimeters on the episiotomy suture for ten days after delivery. In this way, ostrich oil will be purchased from the pharmaceutical market and these tubes will be filled and autoclaved by the respected pharmaceutical consultant.
Category
Treatment - Other

2

Description
Control group: Placebo oil contains an oil-based material (oserin) that is identical in shape, color, and consistency to the drug, in 30-gram oil tubes to be applied twice daily two centimeters across the episiotomy suture for ten days postpartum. will be prepared. Oserin oil will be purchased from the pharmaceutical market and these tubes will be filled and autoclaved by the respected pharmaceutical consultant.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiyeh hospital
Full name of responsible person
Seyyede Zahra Mousavi
Street address
Rajab Niya St, Shishegarkhane St., Fedayian Islam St.,Shush Square, Tehran Town.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
5th Floor, Building No. 2, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran.
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Web page address

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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

Shahid Beheshti 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyede Zahra Mousavi

Position

Master student of midwifery education

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, in front of Shahid Rajaee Heart Hospital, intersection of Ayat Ah... Hashemi Rafsanjani Highway, Vali Asr Ave, Tehran,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Master student of midwifery education

Latest degree

Bachelor

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyede Zahra Mousavi

Position

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available