Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The effect of Nigella sativa cream on pain and wound healing of episiotomy in Primiparous women

Protocol summary

Study aim

This study investigated the effects of nigella sativa cream on pain and wound healing episiotomy was performed.

Design

This study was triple blind clinical trial on 124 women referring to hospital Vali Asr birjand, Iran were chosen purposefully. were selected easy method and then using a randomized block design with Three intervention groups (nigella sativa cream)placebo and control groups.

Settings and conduct

124 primiparous women referring to Valiaser Hospital for normal delivery are selected as samples after gaining the consent of the patients and controlling the inclusion and exclusion criteria. For the first time, Four hours after the completion of episiotomy recovery, and later washing the perineal with saline serum and drying, amount of a knuckle of medication or placebo is used with latex gloves on the wound, in a way that it covers the whole surface. Before intervention and giving tranquilizer,12 hours after intervention and days the first, seventh and tenth after delivery, the patient's perineal pain is measured through McGill's shortened questionnaire.The time cream usage in both groups is two times a day, which continues for ten days. In control group, individuals will receive usual health recommendations according to the country's protocol. On the first, Seventh, and tenth day, wound appearance is checked via the REEDA tool. The researcher and research units were not aware of cream type (medicine , placebo) and the statistical analyzer was not also aware of randomly assignment of research units.

Participants/Inclusion and exclusion criteria

Inclusion criteria: nulliparous women aged 18-35 years old living in the city of Birjand, Iran; at least having the ability to read and write; living with his wife's; body mass index ranging from 19/8-30; non-smoking and no drug dependence; no history of disease impaired wound healing; not using drugs effecting on wound healing; single fetal cephalic; lack of symptomatic infections of the vagina and vulva (the infectious discharge, itching, burning); low blood, anal lesions; vulva and perineum on admission; and rupture of the fetal sac up to 12 hours before the start of pains; lack of stricture restriction pelvic; embryos is vital; the lack of apparent anomalies in the newborn. No rectocel, cystocele severe (grade 2 or higher), wall or mass in the vaginal; no history of obstetric complications, no history of vaginal reconstructive surgery on the Vagina and urethra Exclusion criteria: there interfere with the progress of labor; prolonged second stage of labor longer than 2 hours; delivery devices (vacuum, forceps); delivered via cesarean section; extend the length of the incision or there tear except episiotomy tear; infant hospitalization in the NICU; abnormal vaginal bleeding; shoulder dystocia (leading to the maneuvers other than Robert Mack); manual removal of placenta; hematoma; curettage procedure the first 24 hours after birth; the third stage of labor longer than 30 minutes; no need for episiotomy ,not use the cream on a regular; puerperal fever; complications resulting from the use of Nigella sativa cream: having intercourse to the end of the study (10 days postpartum).

Intervention groups

In the intervention group, nigella sativa cream 0/5 percent of the combined value is Cold Cream with nigella sativa has been used. Units of study nigella sativa cream the size of a finger is placed on the sutures so that the wound is completely covered and do the daily double (each 12h) up ten days. In the group placebo, placebo cream containing simple base cream (Cold Cream) are used. Units of study placebo cream the size of a finger is placed on the sutures so that the wound is completely covered and do the daily double (each 12h) up ten days. In control group, individuals will receive usual health recommendations according to the country's protocol.

Main outcome variables

Pain of episiotomy, Wound healing of episiotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170425033642N1**
Registration date: **2018-01-07, 1396/10/17**
Registration timing: **retrospective**

Last update: **2018-01-07, 1396/10/17**
Update count: **0**

Registration date

2018-01-07, 1396/10/17

Registrant information

Name

Nahid Barati

Name of organization / entity

Faculty of Nursing & Midwifery

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Recruitment status

Recruitment complete

Funding source

Mashhad University Of Medical Sciences

Expected recruitment start date

2017-04-17, 1396/01/28

Expected recruitment end date

2017-10-17, 1396/07/25

Actual recruitment start date

2017-04-17, 1396/01/28

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nigella sativa cream on pain and wound healing of episiotomy in Primiparous women

Public title

The effect of Nigella sativa cream on pain and wound healing of episiotomy in Primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: nulliparous women aged 18-35 years old; living in the city of Birjand, Iran; at least having the ability to read and write; living with his wife's; body mass index ranging from 19/8-30; non-smoking and no drug dependence; no history of disease impaired wound healing; not using drugs effecting on wound healing; single fetal cephalic; lack of symptomatic infections of the vagina and vulva (the infectious discharge, itching, burning); low blood, anal lesions; vulva and perineum on admission; and rupture of the fetal sac up to 12 hours before the start of pains; lack of stricture restriction pelvic; embryos is vital; the lack of apparent anomalies in the newborn. No rectocel, cystocele severe (grade 2 or higher), wall or mass in the vaginal; no history of obstetric complications; no history of vaginal reconstructive surgery on the Vagina and urethra.

Exclusion criteria:

Exclusion criteria: there interfere with the progress of labor; prolonged second stage of labor longer than 2 hours; delivery devices (vacuum, forceps); delivered via cesarean section; extend the length of the incision or there tear except episiotomy tear; infant hospitalization in the NICU; abnormal vaginal bleeding; shoulder dystocia (leading to the maneuvers other than Robert Mack); manual removal of placenta; hematoma; having intercourse to the end of the study (10days postpartum); curettage procedure the first 24 hours after birth; the third stage of labor longer than 30 minutes; the occurrence of an adverse event at 10 days postpartum; no need for episiotomy; not use the cream on a regular; puerperal fever; complications resulting from the use of nigella sativa cream.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **135**
Actual sample size reached: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomly balanced block assignment which is 3 blocks (student, Doctor, midwife) the research units was placed in 3 groups (medicine, placebo , control).

Blinding (investigator's opinion)

Triple blinded

Blinding description

The researcher and research units were not aware of cream type (medicine, placebo) and the statistical analyzer was not also aware of randomly assignment of research units.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University Of Medical Sciences

Street address
School of Nursing and Midwifery, Doktora Intersection , Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2017-01-07, 1395/10/18

Ethics committee reference number
IR.MUMS.REC.1395.486

Health conditions studied

1

Description of health condition studied
Wound healing of episiotomy , pain of episiotomy

ICD-10 code
O90.1

ICD-10 code description
Disruption of perineal obstetric wound

Primary outcomes

1

Description
Pain of episiotomy

Timepoint
Immediately before the intervention,12 hours after intervention and days the first, seventh and tenth after delivery

Method of measurement
McGill Pain Questionnaire short

Secondary outcomes

1

Description
Wound healing of episiotomy

Timepoint
Days the first, ŝeventh and tenth after delivery

Method of measurement
Reeda scale

Intervention groups

1

Description
In the intervention group, nigella sativa cream (0.5 %) percent of the combined value is Cold Cream with nigella sativa has been used. Units of study nigella sativa cream the size of a finger is placed on the sutures so that the wound is completely covered and do the daily double (each 12h) up ten days.

Category
Treatment - Drugs

2

Description
Intervention group: Units of study placebo cream the size of a finger is placed(containing simple base cream) on the sutures so that the wound is completely covered and do the daily double (each 12h) up ten days.

Category
Placebo

3

Description
The control group will be cured at the hospital during the 10 days.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital in Birjand

Full name of responsible person
Nahid Barati

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Avenue ghafari, Birjand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Vice chancellor for research Mashhad University of Medical Sciences

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Barati

Position
MSc of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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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