

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of flaxseed ointment on cesarean wound healing

Protocol summary

Study aim

Determine the effect of flaxseed ointment on cesarean wound healing

Design

A double-blind clinical trial was conducted on 120 women who were selected using spss software and randomly assigned into three intervention groups (referee, placebo) and control.

Settings and conduct

120 women who are referred to Imam Reza Hospital for cesarean section are selected. For the first 24 hours after the cesarean section, the area of the wound is washed with the serum and washed out of the drug or placebo. Duration of ointment in both groups is twice daily for 8 days. The control group receives health recommendations according to the hospital protocol. One-four-eighty-four-day-olds are evaluated with the help of the Rida instrument and the visual scale of the pain. Researcher, statistical analyst and research units of the type of drug (drug, placebo).

Participants/Inclusion and exclusion criteria

Inclusion criteria Age less than 18 years and more than 35 years Gestational age less than 37 or more than 42 weeks At least once previous cesarean section delivery of cesarean section. Baby weighing less than 2500 gr or over 4000 gr Cesarean section with myomectomy or hysterectomy Excessive bleeding that requires blood transfusion. Anomalies manifest in the baby. Extending the operating time for more than an hour Damage to the bladder or abdominal aorta during cesarean section Midwifery problems Expansion of surgical Cure for diseases that impair wound healing. Problems like: death of parents, wife, baby. Failure to enter the study Do not use ointment for more than two days or 6 times dispersed Drug effective on wound healing.

Intervention groups

Patient intervention groups or darunamar use 24 hours a day and then twice daily for 8 days daily. The health advice group is provided based on the routine protocol of the hospital.

Main outcome variables

Healing wound Pain

General information

Reason for update

Acronym

MKC

IRCT registration information

IRCT registration number: **IRCT20180506039552N1**

Registration date: **2018-10-25, 1397/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**

Update count: **0**

Registration date

2018-10-25, 1397/08/03

Registrant information

Name

Maryam Soleimani huni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3251 3806

Email address

soleimanihm951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of flaxseed ointment on cesarean wound healing

Public title

The effect of flaxseed ointment on cesarean wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1.Be Iranian. 2- Resident of Mashhad. 3. The willingness to cooperate in the research, 4-age less than 18 years and more than 35 years.5. Have at least a reading / writing literacy higher than fifth of elementary school. 6- Gestational age less than 37 or more than 42 weeks based on LMP or first trimester ultrasonography. 7- At least once a previous cesarean section. 8. Cesarean Delivery, 9. Classic Hysterotomy Siege. 10. Weight of a baby under 2500 g or over 4000 g. 11 - Live or dead baby 12 - Cesarean section with myomectomy or hysterectomy.13. Excessive bleeding requiring blood transfusion. 14. Significant abnormality in the baby. 15. Longevity of the operation for more than an hour. 16. Damage to the bladder or abdominal aorta during cesarean section. 17. Midwifery problems. 18- Development of surgical incision 19-Distribution of wound healing disorders. 20. Problems such as: the death of parents, spouse, infant.

Exclusion criteria:

1-Do not use ointment for more than 2 days or 6 times dispersed 2- Use of drugs effective on wound healing.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Using SPSS software

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug and drug coding was done by one of the laboratory staff.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

st.Daneshgah,Crossroad.Doktura,st.Ebn Sina.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.023

Health conditions studied

1

Description of health condition studied

Cesarean wound healing

ICD-10 code

090.0

ICD-10 code description

Disruption of caesarean section wound

Primary outcomes

1

Description

Wound healing

Timepoint

After cesarean section (24 hours) and 4th and 8th days after the caesarian section

Method of measurement

Reeda Scale

Secondary outcomes

1

Description

pain

Timepoint

After cesarean section (24 hours) and 4th and 8th days after the caesarian section

Method of measurement

Pain visual scale

Intervention groups

1

Description

Intervention group1: the research unit in the same area as a piece of 5% cotton linen ointment, so that it is completely applied to the surface and done daily twice a day (every 12 hours) for 8 consecutive days

Category

Treatment - Drugs

2

Description

Intervention group 2: the research units in the size of a cuff of the placebo ointment (the base of the ointment) on the suture area, so that it completely covers the surface of the wound and do this twice daily (every 12 hours) for 8 consecutive days It is prescribed.

Category

Placebo

3

Description

Control group: Control group do not receive any drugs; they just receive routine care. The researcher sees them on 5th and 10th days after the caesarian section surgery

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Naderi

Street address

Ebnesina Street

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9137913316

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emamreza@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mosen Tafaghodi

Street address

Ghoreshi building, Daneshgah 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

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

Dr Robab Latifnejad

Position

Vice President of Research and Faculty of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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School of Nursing and Midwifery, Ibn Sina Street

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sedigheh Yousefzadeh

Position

Mashhad University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Full name of responsible person

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Position

Midwifery Master

Latest degree

Bachelor

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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

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