

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The Effect of Calendula ointment on healing and pain localized wound cesarean section in nulliparous women

Protocol summary

Summary

The purpose of this study is to analyze effects of Calendula ointment on healing and pain intensity of cesarean section localized wound in primiparous women. with considering inclusion criteria: (being primiparous women with age range 20-37 years; gestational age 37 - 42 weeks; ability to read and write; Not having history of allergies to any topical medicine; Not addiction to tobacco, drugs and psychotropic; Avoiding use of anticoagulants, antidepressants, anticonvulsants and drugs that weaken the immune system; No history of previous surgical incision cesarean section (above the symphysis pubis); Lack PROM > 18 hours; Not having a body mass index > 35,10; Lateral-lower uterine incision and Pfannenstiel technique skin incision; No accumulation of fat in the abdomen; lack of abnormal vaginal bleeding; Spinal anesthesia; The same type of stitches; Presence of attendant with patient; Using chromic suture to the mucous and silk for skin), Exclusion criteria: (Lack of improper use of marigold ointment or Vaseline ointment based on form was developed according to subjects; unwillingness to continue to participate in the study; using other drugs or methods of healing; using medications affecting wound healing (glucocorticoid - anticoagulant - modulator - broad-spectrum antibiotics - Antihistamines - chemotherapy and radiotherapy); occurring any infection or bleeding at the wound that requires medical intervention with considering random sampling on 108 women who have cesarean incision will be randomly divided into 2 intervention and 1 control group. One of the Intervention groups will use calendula ointment on cesarean incision. the other group will use placebo ointment on cesarean incision every 12 hours. Control group will not use anything on cesarean incision. Our scale to check the pain relieving is VAS ruler and Our scale to check the wound healing is REEDA table. We check the pain and wound healing before intervention then 3 day, 6day and 9 day after starting intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507252248N18**
Registration date: **2015-11-05, 1394/08/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-05, 1394/08/14

Registrant information

Name

Fereshteh Jahdi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00982188773073,00982182471404

Email address

f.jahdi@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-08-04, 1394/05/13

Expected recruitment end date

2016-08-03, 1395/05/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Calendula ointment on healing and pain localized wound cesarean section in nulliparous women

Public title

The Effect of Calendula ointment on healing and pain localized wound cesarean section in nulliparous women

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: (being primiparous women with age range 20-37 years; gestational age 37 - 42 weeks; ability to read and write; Not having history of allergies to any topical medicine; Not addiction to tobacco, drugs and psychotropic; Avoiding use of anticoagulants, antidepressants, anticonvulsants and drugs that weaken the immune system; No history of previous surgical incision cesarean section (above the symphysis pubis); Lack PROM > 18 hours; Not having a body mass index > 35,10; Lateral-lower uterine incision and Pfannenstiel technique skin incision; No accumulation of fat in the abdomen; lack of abnormal vaginal bleeding; Spinal anesthesia; The same type of stitches; Presence of attendant with patient; Using chromic suture to the mucosa and silk for skin), Exclusion criteria: (Lack of improper use of marigold ointment or Vaseline ointment based on form was developed according to subjects; unwillingness to continue to participate in the study; using other drugs or methods of healing; using medications affecting wound healing (glucocorticoid - anticoagulant - immunomodulator - broad-spectrum antibiotics - Antihistamines - chemotherapy and radiotherapy); occurring any infection or bleeding at the wound that requires medical intervention).

Age

From **20 years** old to **36 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery, Iran University of Medical Sciences

Street address

Next to the Mottahari hospital, Rashid Yasmi street, Valiasr avenue

City

tehran

Postal code

Approval date

2015-07-15, 1394/04/24

Ethics committee reference number

IR.IUMS.REC.1394.25011

Health conditions studied

1

Description of health condition studied

healing and pain localized wound cesarean section

ICD-10 code

O86.0

ICD-10 code description

Infection of obstetric surgical wound

Primary outcomes

1

Description

wound healing

Timepoint

before interventional then 3 day, 6day and 9 day after starting intervention.

Method of measurement

wound healing with REEDA table

Secondary outcomes

1

Description

Caesarean wound severity pain

Timepoint

before interventional then 3 day, 6day and 9 day after starting intervention.

Method of measurement

severity pain with VAS

Intervention groups

1

Description

Control group follow the routine of the hospital

Category

N/A

empty

2

Description

mothers put placebo ointment 2 times a day until 10days after birth

Category

Placebo

3

Description

mothers put calendula ointment 2 times a day until 10days after birth

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid Akbaabadi hospital

Full name of responsible person

Akram haghghi khabbaz

Street address

movlavi street

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr seyed ali javad mosavi

Street address

Shahid hemat highway

City

tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Akram Haghghi Khabbaz

Position

Master of science student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty