Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

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

Protocol summary

Summary

Introduction: episiotomy Cutting perineal muscles, with the aim of accelerating the completion of the second phase is to improve the outcome for mother and baby. Drugs with anti-inflammatory effects, antibacterial and antioxidant activity, candidates are suitable for wound healing. Chamomile has all of the above. This study investigated the effects of chamomile cream on wound healing episiotomy was performed. Methods: This study was triple blind clinical trial on 106 women admitted to hospital Omolbanin Mashhad, Iran. Nulliparous women aged 18-35 years, with single fetal cephalic, no history of disease impaired wound healing and not using drugs effecting on wound healing, were selected easy method and then using a randomized block design with two intervention groups (chamomile cream) and control (placebo cream) groups. The labor process control and information related to this process were recorded. If there were a disruption in the progress of labor, delivery devices (vacuum, forceps), have extended the length of the incision or there was tear except episiotomy tear episiotomy the research unit would excluded. Units of study Amount by a finger of prescribed cream (chamomile or placebo) twice daily for 10 days, placed on the sutures. Perineal repair Control Form (Reeda) on days 1,7,10 and 14 after delivery was completed. And the Short Form McGill Pain immediately before the intervention and 1,7,10 and 14 days after the delivery was completed by the researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051413336N1**
Registration date: **2013-12-25, 1392/10/04**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-12-25, 1392/10/04

Registrant information

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School of Nursing and Midwifery Mashhad
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2013-10-26, 1392/08/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: nulliparous women aged 18-35 years old living in the city of Mashhad, 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, use of acetaminophen suppository in 6 hours before delivery; 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; having intercourse to the end of the study (15 days 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 15 days postpartum; no need for episiotomy; not use the cream on a regular; puerperal fever; complications resulting from the use of chamomile cream.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

khorasan razave

City

Mashhad

Postal code

Approval date

2013-06-22, 1392/04/01

Ethics committee reference number

911324

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 to 2 weeks after intervention

Method of measurement

McGill Pain Questionnaire short

2

Description

Wound healing of episiotomy

Timepoint

First Day of episiotomy repair to 14 days

Method of measurement

Scale reeda

Secondary outcomes

1

Description

The rate of pain episiotomy

Timepoint

Immediately prior to the 2-week after the start of the intervention intervention.

Method of measurement

Questionnaire McGill Pain short

2

Description

The rate of wound healing of episiotomy

Timepoint

First Day of episiotomy repair to 14 days

Method of measurement

Scale reeda

Intervention groups

1

Description

In the intervention group, chamomile cream 1/3 percent of the combined value is Cold Cream with Chamomile has been used. Units of study Chamomile 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

In the control group of 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.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized Women's Hospital, Mashhad Omolbanin (SA), Mashhad University of Medical Sciences

Full name of responsible person

Azhari sedigheh, MS Nursing, Midwifery Training

Street address

Khorasan Razavi, Mashhad, Intersection Zarineh, Omolbanin Women's Hospital (SA)

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Mashhad University of Medical Sciences

Full name of responsible person

Dr.tafaghodi

Street address

Khorasan Razavi, Mashhad University Avenue, Building Qureshi

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Mashhad 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

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Aradmehr

Position

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Other areas of specialty/work

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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