

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison effect of Calendula and Turmeric(Curcuma Longa) ointment on healing and pain severity of episiotomy in primiparous women attending selected hospital of shiraz university of medical sciences 2015-1016.

Protocol summary

Summary

My objective is to test the comparison effect of Calendula and Turmeric(Curcuma Longa) ointment on healing and pain severity of episiotomy in primiparous women. 90 women who have episiotomy will be randomly divided into 2 intervention and 1 control group. one of the Intervention group will use Calendula ointment the other group will use Turmeric(Curcuma Longa) ointment on episiotomy incision every 8 hours. Control group will use Placebo on episiotomy incision. All groups in the ointment, receive routine care hospital. Our scale to check the wound healing is REEDA table. We check the healing process before and 3,7,10 , 14 days after intervention. Our scale to check the pain reliving is VAS ruler. We check the pain before and 3,7,10 , 14 days after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072023265N1**
Registration date: **2015-08-10, 1394/05/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-10, 1394/05/19

Registrant information

Name

Elahe Mahmoudi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 4352 6842

Email address

stud2420062868@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Calendula and Turmeric(Curcuma Longa) ointment on healing and pain severity of episiotomy in primiparous women attending selected hospital of shiraz university of medical sciences 2015-1016.

Public title

Comparison effect of Calendula and Turmeric(Curcuma Longa) ointment on healing and pain severity of episiotomy.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being primiparous; gestational age 37 to 42 weeks; vaginal delivery with episiotomy medio-

lateral; having a singleton live child; cephalic presentation; pre-pregnancy body mass index less than 30; absence of reconstructive surgery on the vagina and perineum; do not use medications that effect wound healing; no specific disease(Anemia, cardiovascular disease, diabetes, immune deficiency, liver disease, depression, absence of coagulation disorders, preeclampsia, infectious diseases); lack of extending the incision and into the 3, 4 grade laceration or rupture exist except episiotomy. Exclusion criteria: manual removal of placenta; postpartum hemorrhage; hematoma formation; postpartum fever and chills(fever > 38); manipulation of the perineum after delivery; episiotomy infections; need to re-stitch the episiotomy; the use of any ointment or cream other than what the researcher receives, Cause skin allergy by the use of ointment; unwillingness to continue to participate in the study.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2015-06-21, 1394/03/31

Ethics committee reference number

IR.SUMS.REC.1394.40

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

O90.1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes

1

Description

Severity of episiotomy pain

Timepoint

Before intervention then 3,7,10,14 days after intervention

Method of measurement

Visual Analogue Scale(VAS)

Secondary outcomes

1

Description

Healing of episiotomy

Timepoint

Before intervention then 3,7,10,14 days after intervention

Method of measurement

REEDA (Redness, Edema, Ecchymosis, Discharge, Approximation).

2

Description

Number of Mefenamic acid capsules used

Timepoint

Tenth day after delivery

Method of measurement

count of remaining Capsules

Intervention groups

1

Description

Group1: mothers put Calendula on episiotomy 3 times a day of a knuckle until 7 days after birth.

Category

Treatment - Drugs

2

Description

Group2: mothers put Turmeric on episiotomy 3 times a day of a knuckle until 7 days after birth.

Category

Treatment - Drugs

3

Description

Control group: mothers put Placebo on episiotomy 3 times a day of a knuckle until 7 days after birth.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Miss Elahe Mahmoudi

Street address

Hafez Hospital, Chamran Boulevard

City

Shiraz

2

Recruitment center

Name of recruitment center

Zeynab Hospital

Full name of responsible person

Miss Elahe Mahmoudi

Street address

Zeynab Hospital, Zeynabiyeh Boulevard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Gholam Reza Hatam

Street address

7th Floor, Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Masoume Kaviani

Position

Master's degree in Midwifery, Faculty member

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