Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of combination of Chamomile and Calendula oficinalis on Episiotomy wound healing and pain in nulliparous women

Protocol summary

Summary

The aim of this study is to determine the effect of combination of Chamomile and Calendula oficinalis on healing and pain intensity of episiotomy in primiparous women. This randomized clinical trial will be done on 99 primiparous women admitting in Akbarabadi hospital. Incluson criteria contain: being primiparous women with age range 18-35 years; gestational age 37-42 weeks; single pregnancy; cephalic presentation; ability to read and write; living with his wife's; insensitivity to special herbal drugs in past; non-smoking and no drug dependence; no history of disease impaired wound healing; Lack PROM more than 18 hours; absence of reconstructive surgery on the vagina and perineum; No rectocel, cystocele severe (grade 2 or higher), wall or mass in the vagina; mediolateral episiotomy without rupture and spread with same amount of Lidocaine; lack of volvo and vaginal inflammation at the beginning of research; body mass index less than 30; and Exclusion criteria contain: there interfere with the progress of labor; prolonged second stage of labor longer than 2 hours; extend the length of the incision or there tear except episiotomy tear; 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 (10 days postpartum); curettage procedure the first 24 hours after birth; not use the ointment on a regular; puerperal fever; an infection of episiotomy; need to re-stitch the episiotomy. Eligible women will be randomly divided into three Intervention, Placebo and control groups. the Intervention group will use Combined ointment, and the placebo group will use Placebo ointment on episiotomy incision every 8 hours. Control group will not use anything on episiotomy incision. Our scale to check the wound healing is REEDA table and Our scale to check the pain reliving is VAS rule. We check the wound healing and pain before intervention (4 hours after delivery) then1 day, 5 day and 10 day after starting intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102624712N1**
Registration date: **2015-12-11, 1394/09/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-12-11, 1394/09/20

Registrant information

Name

Homa Sadeghi Aval Shahr

Name of organization / entity

Nursing & Midwifery Faculty University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, school of Nursing and Midwifery, Iran University of Medical Scienc

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of combination of Chamomile and Calendula oficinalis on Episiotomy wound healing and pain in nulliparous women

Public title
The effect of combination of Chamomile and Calendula oficinalis on Episiotomy wound healing and pain in nulliparous women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: being primiparous women with age range 18-35 years; gestational age 37-42 weeks; single pregnancy; cephalic presentation;ability to read and write; living with his wife's; insensitivity to special herbal drugs in past; non-smoking and no drug dependence; no history of disease impaired wound healing; Lack PROM more than 18 hours; absence of reconstructive surgery on the vagina and perineum; No rectocel, cystocele severe (grade 2 or higher), wall or mass in the vagina; mediolateral episiotomy without rupture and spread with same amount of Lidocaine; lack of volvo and vaginal inflammation at the beginning of research; body mass index less than 30;. Exclusion criteria: there interfere with the progress of labor; prolonged second stage of labor longer than 2 hours; extend the length of the incision or there tear except episiotomy tear; 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 (10 days postpartum); curettage procedure the first 24 hours after birth; not use the ointment on a regular; puerperal fever; an infection of episiotomy; need to re-stitch the episiotomy.

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Vice chancellor for Research Iran University of Medical Sciences

Street address
Hemmat freeway (beside Milad Tower), Tehran

City
Tehran

Postal code

Approval date
2015-11-11, 1394/08/20

Ethics committee reference number
IR.IUMS.REC.1394.9211373215

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
Episiotomy wound healing

Timepoint
4 hours after delivery, 1 days after delivery, 5 days after delivery ,and 10 days after delivery

Method of measurement
REEDA Scale of wound healing

2

Description
Pain in episiotomy

Timepoint
4 hours after delivery, 1 days after delivery, 5 days after delivery ,and 10 days after delivery.

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Sedative tablets counting

Timepoint
Tenth day after delivery

Method of measurement
questionnaire

Intervention groups

1

Description
The intervention group: Combined ointment 3 times a day(each 8 hours) for 10 days as much as one finger (equivalent to about 20 mlligrams) to be applied topically on the site of episiotomy
Category
Treatment - Drugs

2

Description
The placebo group: Placebo ointment 3 times a day(each 8 hours) for 10 days as much as one finger (equivalent to about 20 mlligrams) to be applied topically on the site of episiotomy.
Category
Placebo

3

Description
Control group follow the routine of the hospital
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar Abadi Hospital
Full name of responsible person
Bahare Davami
Street address
Molavi Street, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, School of Nursing and Midwifery, Iran University of Medical Scienc
Full name of responsible person
Dr Frough Rafiea , Dr Ali Javad Mosavi
Street address
Hemmat freeway (beside Milad Tower), Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research, School of Nursing and Midwifery, Iran University of Medical Scienc
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
School of Nursing and Midwifery, Iran University of Medical Sciences
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Person responsible for updating data

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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