Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessing the effect of the ointment of green tea on the intensity of episiotomy pain and wound healing in primiparous women

Protocol summary

Summary

The aim of this study is to assess the effect of Green tea ointment on perineal pain and healing of episiotomy wound. In this double-blind, randomized, placebo-controlled trial, 99 postpartum women will be allocated into three groups. They will receive green tea or placebo ointment or betadin. They will be instructed to wash hands and the perineum thoroughly and dry it with a clean tissue every time before using the ointment, then put a length of one knuckle of ointment (approximately 2 cm) on the stitch area after 1-2 min using a sterile pad. This procedure will be repeated twice daily for 10 d. Perineal pain and wound healing will be assessed by using visual analogue scale and REEDA scale (0-15), before the intervention and 12 hours after delivery, 5 and 10 days postpartum. The investigators and participants will unaware of the type of ointment given to every participant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011225983N1**
Registration date: **2016-04-01, 1395/01/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-01, 1395/01/13

Registrant information

Name
Hadis Shahrahmani
Name of organization / entity
School of Nursing and Midwifery of Shahid Beheshti
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Iran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of the ointment of green tea on the intensity of episiotomy pain and wound healing in primiparous women

Public title

Assessing the effect of the ointment of green tea on the intensity of episiotomy pain and wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primiparous woman; gestational ages between 37 to 42 weeks; aged 18 to 35 year; BMI between 19.8-30 kg/m2; resident in kerman; was educated; singleton birth with cephalic presentation; child weigh between 2500 to 4000 grams; have a vaginal delivery with mediolateral episiotomy without instrumental delivery and without tears; no rupture of membranes more than 24 hours; not eclampsia and pre-

eclampsia; no manual removal of placenta; not taking the first stage of labor (more than 14 hours) and the second stage of labor (more than 2 hours) and the third stage of labor (more than 30 minutes); no fetal anomaly or bedfast to the neonatal unit; have hematoma episiotomy; no addiction; no allergies to topical drugs; the lack of diseases such as chronic systemic disorders, cardiovascular, respiratory, coagulation disorders and connective tissue, diabetes, anemia, immunosuppressant, hemophilia, malnutrition and psychological disorders; no history of injury, or previous surgery of lesions visible in the perineum (genital warts, hemorrhoids), persistent constipation Exclusion criteria: do not visit for care; not interested to continue to participate in the study; do not use the ointment properly and as directed; do not use the betadin properly and as directed; allergic to use ointment; have a sex in the first 5 days after birth; manipulation of the perineum after episiotomy repair; Severe bleeding after childbirth; use drugs on wound healing (anticoagulant, antidepressants, antiepileptic, alcohol, immunosuppressant drugs, antibiotics, chemotherapy) during the study

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)
Double 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 Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Velenjak St, Shahid Chamran Highway, Tehran, Iran

City
Tehran

Postal code
1985717443

Approval date
2015-07-13, 1394/04/22

Ethics committee reference number
SBMU2.REC.1394.9

Health conditions studied

1

Description of health condition studied
episiotomy

ICD-10 code
O70.1

ICD-10 code description
Second degree perineal laceration during delivery

Primary outcomes

1

Description
Intensity of episiotomy pain

Timepoint
before intervention, 12 hours, 5 and 10 days postpartum.

Method of measurement
Visual Analogue Scale (VAS)

2

Description
wound healing of episiotomy

Timepoint
before intervention, 12 hours, 5 and 10 days postpartum.

Method of measurement
REEDA scale

Secondary outcomes

empty

Intervention groups

1

Description
Green tea ointment is used as much as one knuckle (2cm) on episiotomy wounds twice per day for 10 days.

Category
Treatment - Drugs

2

Description
placebo ointment is used as much as one knuckle (2cm) on episiotomy wounds twice per day for 10 days.

Category
Placebo

3

Description

betadin, 3 times a day for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Hadis Shahrahmani

Street address

Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Velenjak St, Shahid Chamran Highway, Tehran, Iran

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 Shahid Beheshti 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

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Full name of responsible person

Hadis Shahrahmani

Position

Master of Science University Student of Midwifery

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