

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of Hypericum Perforatum cream on the episiotomy wound healing and common discontent after childbirth in primiparous women

Protocol summary

Summary

The purpose of this study is evaluating the effect of hypericum perforatum cream on the episiotomy wound healing and common discontent after childbirth in primiparous women. This randomized double-blind clinical trial will do on 100 nulliparous women with mediolateral episiotomy who admitted in Talesh shahid noorani hospital. The creams will produce by advicer pharmacist in Shahid Beheshti pharmacy faculty in similar color and will put into similar tubes with label A and B. then will give the participants after checking the inclusion and exclusion criteria, with randomized method. And will ask from participants to use topically one finger of the cream on episiotomy wounds twice for ten days. Perineal pain intensity and wound healing will be evaluated in first 12 hours and 5,10 days after delivery by using Visual Analogue Scale (VAS) and REEDA scoring scale. Common postpartum discontent will be assessed with scholar made questionnaire on 10th day.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501253860N12**
Registration date: **2015-04-29, 1394/02/09**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-29, 1394/02/09

Registrant information

Name

Gity Ozgoli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research of school of nursing and midwifery Shahid Beheshti university of medical sciences. Dr Kiandokht Ghanati

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-04-19, 1394/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Hypericum Perforatum cream on the episiotomy wound healing and common discontent after childbirth in primiparous women

Public title

The effect of Hypericum Perforatum cream on the episiotomy wound healing and common discontent after childbirth in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primiparous woman; aged 18 to 35 years; have a vaginal delivery with mediolateral episiotomy without instrumental delivery and tears; singleton birth with cephalic presentation; was educated; resident in talesh; gestational ages must be between 37

to 42 weeks; child weights must be between 2500 to 4000 grams; the lack of diseases history such as chronic systemic disorders; cardiovascular; Respiratory; coagulation disorders and connective tissue; diabetes; anemia; immunosuppressant; hemophilia; malnutrition and psychological disorders; no allergies to topical drugs; no rupture of membranes more than 24 hours; no addiction; BMI between 19.8-30 kg/m²; no manual removal of placenta; no fetal anomaly or bedfast to the neonatal unit; 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 1 hours). Exclusion criteria: do not visit for care; do not use hypericum cream properly and as directed; not interested to continue to participate in the study; not allergy to use hypericum cream; have a sex in the first 5 days after birth; manipulation of the perineum after episiotomy repair; use drugs on wound healing (anticoagulant, antidepressants, antiepileptic, alcohol, glucocorticoids; immunosuppressant drugs) during the study; not have episiotomy hematoma in the first 24 hours after delivery.

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: **100**

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

Tehran, Shahid Abbas poor Street

City

Tehran

Postal code**Approval date**

2015-01-19, 1393/10/29

Ethics committee reference number

1000/2578

Health conditions studied**1****Description of health condition studied**

Episiotomy

ICD-10 code

090/1

ICD-10 code description

Disruption of perineal obstetric wound

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

3**Description**

common discontent after childbirth

Timepoint

10days after delivery

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Sedative tablets counting

Timepoint

10 day after delivery

Method of measurement

questionnaire

Intervention groups**1****Description**

Intervention group: Hypericum cream (produced in

Shahid Beheshti pharmacy faculty) uses topically one finger amount (2cm) on episiotomy wounds twice for 10 days.

Category

Treatment - Drugs

2**Description**

In control group; placebo cream (produced in Shahid Beheshti pharmacy faculty) uses topically one finger amount (2cm) on episiotomy wounds twice for 10 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Noorani Hospital

Full name of responsible person

Somaye Yahya

Street address**City**

Talesh

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

vice chancellor for research of school of nursing and midwifery Shahid Beheshti university of medic

Full name of responsible person

Dr Kiandokht Ghanati

Street address

Shahid Abbaspoor street, Valiasr St, 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 of school of nursing and midwifery Shahid Beheshti university of medic

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 of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Gity Ozgoli

Position

Phd of Midwifery

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Full name of responsible person

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Position

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Web page address**Person responsible for updating data****Contact****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