

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Impact of Hypericum ointment on perineal pain and episiotomy healing

Protocol summary

Summary

The purpose of this study is evaluating the effect of Hypericum ointment on perineal pain and episiotomy healing. This randomized triple-blind clinical trial will be done on 84 nulliparous women who were admitted in Tehran Baharloo hospital (With inclusion criteria contain: Full term singleton pregnancy with cephalic presentation; absence of rapid or prolonged labor; absence of membranes for more than 18 hours; mediolateral episiotomy without rupture and spread with same amount of Lidocaine; lack of visible damage or defects in the perineal area; Absence of illness; addiction and drugs that influence on wound healing; Spontaneous and complete placenta outflow; Apparently healthy infant with normal weight; and Exclusion criteria contain: Episiotomy hematoma in the first 24 hours after childbirth; Failure to use the correct and consistent command of Hypericum ointment and placebo; Unwillingness to continue participating in the study; Sensitivity to ointments; Having sexual relation for the first 10 days of postpartum). Eligible women will be allocated to the prevention and control groups with block randomization. Ointments (made by pharmaceutical industries Dineh Iran) will be used 2 times a day and for 10 days with amount of one knuckle (about 3 grams) by mother. Pain in 5 innings (4, 8.12 hour, 5 and 10 days after episiotomy) and wound healing 5 and 10 days after episiotomy will be evaluated .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404085912N15**
Registration date: **2014-04-18, 1393/01/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-04-18, 1393/01/29

Registrant information

Name

Mandana Mir Mohammad Ali Ei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6692 7171

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Recruitment status

Recruitment complete

Funding source

Research Department of Tehran University of Medical Sciences

Expected recruitment start date

2014-04-30, 1393/02/10

Expected recruitment end date

2014-10-02, 1393/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of Hypericum ointment on perineal pain and episiotomy healing

Public title

Impact of Hypericum ointment on perineal pain and episiotomy healing

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Full term singleton pregnancy with cephalic presentation; absence of rapid or prolonged

labor; absence of membranes for more than 18 hours; mediolateral episiotomy without rupture and spread with same amount of Lidocaine; lack of visible damage or defects in the perineal area; Absence of illness, addiction and drugs that influence on wound healing; Spontaneous and complete placenta outflow; Apparently healthy infant with normal weight; and Exclusion criteria: Episiotomy hematoma in the first 24 hours after childbirth; failure to use the correct and consistent command of Hypericum ointment and placebo; unwillingness to continue participating in the study; sensitivity to ointments; having sexual relation for the first 10 days of postpartum.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple 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 Tehran University of Medical Sciences

Street address

6th floor, Central building, Ghods street, Bolvar Keshavarz, Tehran

City

Tehran

Postal code**Approval date**

2014-03-05, 1392/12/14

Ethics committee reference number

130/2949/92/3

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**

Pain intensity

Timepoint

4 hours after episiotomy, 8 hours after episiotomy, 12 hours after episiotomy, 5 days after episiotomy, 10 days after episiotomy.

Method of measurement

Visual Analogue Scale

2**Description**

Healing of episiotomy

Timepoint

Before intervention, 5 and 10 days after episiotomy

Method of measurement

REEDA Scale of wound healing

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

Sedative tablets counting

Timepoint

Tenth day after delivery

Method of measurement

Counted tablets

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

The intervention group: Hypericum ointment 2 times a day for 10 days (preparation and packaging by Dineh Iran company) as much as one finger (equivalent to about 3 grams) to be applied topically on the site of episiotomy.

Category

Treatment - Drugs

2**Description**

The control group: Placebo ointment 2 times a day for 10 days (preparation and packaging by Dineh Iran company) as much as one finger (equivalent to about 3 grams) to be applied topically on the site of episiotomy.

Category

Placebo

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

Tehran Baharloo Hospital

Full name of responsible person

Vakil Ghahani Farzaneh

Street address

Behdari St, Rahahan Sq

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

Research department of Tehran University of Medical Science

Full name of responsible person

Dr Fotoohi Akbar

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6th floor, central building, near Ghods ST, Bolvar Keshavarz

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research department of Tehran University of Medical Science

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**

Tehran University of Medical Sciences

Full name of responsible person

Mir Mohammad Ali Ei Mandana

Position

Scientific Instructor

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Web page address

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