Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 randomize triple-blind clinical trial will done on 84 nulliparous women who 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 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

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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, Centeral 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/د

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 Analouge 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
City
Tehran

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
Street address
6th floor, centeral building, near Ghods ST, Bolvar Keshavarz
City
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
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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