

# 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)

###### Phone

+98 21 6692 7171

###### Email address

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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

**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, central 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mir Mohammad Ali Ei Mandana

**Position**

Scientific Instructor

**Other areas of specialty/work****Street address**

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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*