

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### The effect of *Achillea millefolium* and *Hypericum perforatum* ointments on episiotomy wound healing in primiparous women

#### Protocol summary

##### Summary

As the episiotomy has physiologic, psychologic and social - economical consequences so, not only the decision to do it but also the manner of performance and the quality of future cares, are important. In traditional medicine, topical usage of *Achillea millefolium* and *Hypericum perforatum* oil has showed significant affects on wounds healing. The purpose of this study was assessed the efficacy of *Achillea millefolium* and *Hypericum perforatum* ointments on episiotomy wound healing in primiparous women. This study is a double blind clinical trial that was performed on 140 primiparous women qualified for the research. After delivery, mothers in one group took no interventions, other groups took placebo ointment, *Hypericum perforatum* and *Achillea millefolium* ointments 5%, twice a day for ten days. The healing process was assessed by 5 specifications: redness, ecchymosis, edema, discharge and wound dehiscence at 7th, 10th and 14th days after delivery, pain level was assessed by means of visual analogue scale. Findings of this study showed that there was significant difference between groups in perineal pain level at 7th & 10th & 14th, redness and edema at 7th & 10th and ecchymosis at 7th days postpartum, as pain level, redness, edema and ecchymosis in groups who consume *Hypericum perforatum* and *Achillea millefolium* ointments were less than control groups ( $P < 0.05$ ). But discharge and dehiscence incidence showed no significant difference between groups ( $P > 0.05$ ).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016072629084N1**

Registration date: **2016-08-08, 1395/05/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-08, 1395/05/18

##### Registrant information

###### Name

Atefeh Keivani

###### Name of organization / entity

Shahrekord University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3225 1195

###### Email address

ati.keyvani@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Shahrekord University of Medical Sciences

##### Expected recruitment start date

2012-10-22, 1391/08/01

##### Expected recruitment end date

2013-04-20, 1392/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of *Achillea millefolium* and *Hypericum perforatum* ointments on episiotomy wound healing in primiparous women

##### Public title

The effect of *Achillea millefolium* and *Hypericum perforatum* ointments on episiotomy wound healing

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: • Being nulliparous • Gestational age of 37-42 weeks • Having a single fetus • Not to use particular medications (such as glucocorticoids, anticoagulant, chemotherapy, immunosuppressant and radiotherapy) • No history of the diseases that disrupt wound healing process such as chronic systemic diseases, cardiac, renal, pulmonary diseases, coagulation disorders, immune deficiency, connective tissue disorder and diabetes • Not having anemia, mental illnesses, persistent constipation, hemorrhoid, hemophilia and malnutrition • no allergic history of herbal medicines • Body mass index of 19/8-26 • having no active skin diseases such as allergic disorders, skin irritation or wound in Incision site and symptomatic vaginitis • Not using antibiotics after episiotomy • no history of perineal repair surgery • no history of genital warts Exclusion criteria: • Cephalopelvic disproportion in pelvic exam • Disruption in labor progress (first delivery stage > 20hours, and prolonged second delivery stage > 2hours (prolonged labor) or cervical dilation progress ≥ 5cm in hour or labor duration < 3hours (fast Delivery)) • Manual placental removal • Third and fourth degree perineal laceration • prolonged membrane Rupture (> 18hours) • abnormal postpartum hemorrhage or hematoma • irregular use of ointment (< 7days or 14 times) • onset complications such as itching or skin irritation

### **Age**

No age limit

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: **140**

### **Randomization (investigator's opinion)**

Not 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 Shahrekord University of Medical Sciences

### **Street address**

Kashani avenue

### **City**

Shahrekord

### **Postal code**

8815713471

### **Approval date**

2011-08-21, 1390/05/30

### **Ethics committee reference number**

14\_5\_90

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

episiotomy wound

#### **ICD-10 code**

O90.1

#### **ICD-10 code description**

Disruption of perineal obstetric wound

## **Primary outcomes**

### **1**

#### **Description**

pain level

#### **Timepoint**

Patient explained perineal pain level by a number of 0-10 at second, 7th & 10th & 14th days postpartum

#### **Method of measurement**

visual analogue scale

### **2**

#### **Description**

The healing process by 5 specifications: redness, ecchymosis, edema, discharge and wound dehiscence

#### **Timepoint**

at 7th, 10th and 14th days after delivery

#### **Method of measurement**

researcher assessed redness, edema and ecchymosis in millimeters and charted in perineal repair control form

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

control group: non-intervention

#### **Category**

Other

### **2**

#### **Description**

control group: consuming placebo ointment. Placebo

ointment was Vaseline without extract in 30gr tubes. The patients were selected among women who referred to shahrekord health centers for routine prenatal visits. Before delivery they received necessary training about how care the sutures, personal hygiene, nutrition and physical activity, then they received one coded ointment and educated how to use: first, the perineum should be washed and dried, then at second day postpartum they were asked to use 1cm of ointment on episiotomy site (the sutures), so that ointment cover all surface of incision, then a pad was used; this was continued twice a day for ten days.

#### Category

Placebo

#### 3

##### Description

case group: consuming Achillea millefolium ointment. Achillea millefolium purchased from medical plants sellers and after proving the identity by Medical Plants Research Center of Shahrekord University of Medical Sciences, made broken then extracted by using Ethanol %90 solution. The acquired hydroalcoholic extract condensed until became dry and this condensed extract packed with sterile Vaseline as base (%5 weight ratio) in 30gr tubes. The patients were selected among women who referred to shahrekord health centers for routine prenatal visits. Before delivery they received necessary training about how care the sutures, personal hygiene, nutrition and physical activity, then they received one coded ointment and educated how to use: first, the perineum should be washed and dried, then at second day postpartum they were asked to use 1cm of ointment on episiotomy site (the sutures), so that ointment cover all surface of incision, then a pad was used; this was continued twice a day for ten days.

#### Category

Treatment - Drugs

#### 4

##### Description

case group: consuming Hypericum perforatum ointment. Hypericum perforatum purchased from medical plants sellers and after proving the identity by Medical Plants Research Center of Shahrekord University of Medical Sciences, made broken then extracted by using Ethanol %90 solution. The acquired hydroalcoholic extract condensed until became dry and this condensed extract packed with sterile Vaseline as base (%5 weight ratio) in 30gr tubes. The patients were selected among women who referred to shahrekord health centers for routine prenatal visits. Before delivery they received necessary training about how care the sutures, personal hygiene, nutrition and physical activity, then they received one coded ointment and educated how to use: first, the perineum should be washed and dried, then at second day postpartum they were asked to use 1cm of ointment on episiotomy site (the sutures), so that ointment cover all surface of incision, then a pad was used; this was continued twice a day for ten days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

health center number 2

##### Full name of responsible person

##### Street address

##### City

shahrekord

### 2

#### Recruitment center

##### Name of recruitment center

health center number 3

##### Full name of responsible person

##### Street address

##### City

shahrekord

### 3

#### Recruitment center

##### Name of recruitment center

Mirabad health center

##### Full name of responsible person

##### Street address

##### City

shahrekord

### 4

#### Recruitment center

##### Name of recruitment center

Hajar hospital

##### Full name of responsible person

##### Street address

##### City

shahrekord

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Full name of responsible person

Vice-Chancellor for Research and Technology Affairs

##### Street address

Kashani avenue

##### City

shahrekord

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

**Title of funding source**

Shahrekord 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**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Atefeh Keivani

**Position**

medical doctor

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

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Maryam Hajhashemi

**Position**

gynaecologist

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Shahrekord University of Medical Sciences

**Full name of responsible person**

Atefeh Keivani

**Position**

medical doctor

**Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Fax****Email****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*