

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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Postal code**Phone**

003832251195

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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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Kashani avenue

City

shahrekord

Postal code**Phone**

003833349507

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hajhashemy73@yahoo.com

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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*