

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Quercus persica L and Lawsonia inermis L ointment on episiotomy wound healing in primiparous women in 2014-2015

Protocol summary

Summary

Study Purpose: Investigation effect of Quercus persica L and Lawsonia inermis L ointment on episiotomy wound healing in primiparous women Study Plan: Interventional, Randomized, Double Blind, Used Placebo, Single Center, One stage trial Study Samples: Primiparous women which came to Hajar Hospital of Shahrekord city in 2014 to 2015 Inclusion Criteria: Nullipar (Gravid 1); Pregnancy age 37-42 weeks; Singleton fetus; Not Using special drugs; No disease history; Pulmonary; Sensitivity to herbal medicines; BMI between 19.8 to 26 Exclusion Criteria: History reconstructive surgery on perineal; Failure to comply with the fetus in the mother's pelvis, pelvic examination; Interfere with the progress of labor; Manual removal of placenta; 3rd and 4th degree perineal tear; Prolonged rupture of membrane; Using of vacuum and forceps; abnormal bleeding or hematoma after delivery; Genital Warts; use irregularly ointment Sample Size: 160 Intervention: using cream twice per day for 10 days, the groups are as below: 1- No intervention 2- Placebo Cream 3- 5% Lawsonia inermis Cream 4- 2% Quercus persica Cream Each group consist of 40 samples which after elimination of deviations will be 30 samples at least. Primary outcome measure: Redness, Edema, Bruising, Secretion and Distance between edges of wound

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060122521N1**

Registration date: **2015-06-27, 1394/04/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-27, 1394/04/06

Registrant information

Name

Sanaz Zibanejad

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 3330 0613

Email address

zibanejad@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Quercus persica L and Lawsonia inermis L ointment on episiotomy wound healing in primiparous women in 2014-2015

Public title

The effect of Quercus persica L and Lawsonia inermis L ointment on episiotomy wound healing in primiparous women in 2014-2015

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Nullipar (Gravid 1); Pregnancy age 37-42 weeks; Singleton fetus; Not Using special drugs as Glucocorticoids, Anticoagulant, Chemotherapy, Suppression of the immune or Radiotherapy; No disease history as impair the healing of chronic diseases such as systemic, heart, renal, Pulmonary, Coagulopathy, Immunocompromised, Connective tissue disorders, Diabetes, Anemia, Mental, Persistent constipation, Hemorrhoids, Hemophilia; Malnutrition; Sensitivity to herbal medicines; BMI between 19.8 to 26; Active skin disease such as allergic disorders; Scar or skin allergy; BV symptoms Exclusion Criteria: History reconstructive surgery on perineal; Failure to comply with the fetus in the mother's pelvis, pelvic examination; Interfere with the progress of labor (first stage more than 20 hours or second stage more than 2 hours or Cervical dilatation more than 5 cm per hour Fast Vaginal delivery); Manual removal of placenta; 3rd and 4th degree perineal tear; Prolonged rupture of membrane (more than 18 hours); Using of vacuum and forceps; abnormal bleeding or hematoma after delivery; Genital Warts; use irregularly ointment

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

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**

Shahrekord University of Medical Sciences

Street address

Kashani Blvd., Shahrekord

City

Shahrekord

Postal code

8815713471

Approval date

2014-01-26, 1392/11/06

Ethics committee reference number

1023

Health conditions studied**1****Description of health condition studied**

Infection of obstetric surgical wound

ICD-10 code

O86.0

ICD-10 code description

Infection of obstetric surgical wound

2**Description of health condition studied**

Haematoma of obstetric wound

ICD-10 code

O90.2

ICD-10 code description

Haematoma of obstetric wound

3**Description of health condition studied**

Dehiscence of episiotomy wound

ICD-10 code

O90.1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes**1****Description**

Wound Healing

Timepoint

Days 7, 10 and 14

Method of measurement

Reeda Scale

2**Description**

Edema

Timepoint

Days 7, 10 and 14

Method of measurement

Reeda Scale

3**Description**

Bruising

Timepoint

Days 7, 10 and 14

Method of measurement

Reeda Scale

4

Description

Secretion

Timepoint

Days 7, 10 and 14

Method of measurement

Reeda Scale

5

Description

Distance between edges of wound

Timepoint

Days 7, 10 and 14

Method of measurement

Reeda Scale

6

Description

Redness

Timepoint

Days 7, 10 and 14

Method of measurement

Reeda Scale

Secondary outcomes

1

Description

Pain Intensity

Timepoint

Days 7, 10 and 14

Method of measurement

Pain Perception Scale

Intervention groups

1

Description

5% Lawsonia inermis Cream, 1 cm, Twice per day, 10 days

Category

Treatment - Drugs

2

Description

Placebo (Osirin) Cream, 1 cm, Twice per day, 10 days

Category

Placebo

3

Description

2% Quercus persica Cream, 1 cm, Twice per day, 10 days

Category

Treatment - Drugs

4

Description

Non Intervention Group

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Hajar Hospital of Shahrekord

Full name of responsible person

Dr. Sanaz Zibanejad

Street address

Kashani Blvd., Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Sepideh Miraj

Street address

Hajar Hospital of Shahrekord

City

Shahrekord

Grant name**Grant code / Reference number**

1548

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

Dr. Sanaz Zibanejad

Position

PHD in Medical Science

Other areas of specialty/work

Street address

Hajar Hospital of Shahrekord

City

Shahrekord

Postal code

8815713471

Phone

+98 38 3222 0016

Fax

+98 38 3224 3715

Email

Zibanejad@skums.ac.ir

Web page address

www.skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Sepideh Miraj

Position

PhD in Gynecology

Other areas of specialty/work

Street address

Shahrekord University of Medical Sciences

City

Shahrekord

Postal code

8815713471

Phone

+98 38 3222 0016

Fax

+98 38 3224 3715

Email

SepidehMiraj@skums.ac.ir

Web page address

www.skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Sanaz Zibanejad

Position

PHD in Medical Sciences

Other areas of specialty/work

Street address

Hajar Hospital of Shahrekord

City

Shahrekord

Postal code

8815713471

Phone

+98 38 3222 0016

Fax

+98 38 3224 3715

Email

Zibanejad@skums.ac.ir

Web page address

www.skums.ac.ir

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