

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison the effect of cooling gel pads and topical olive oil on the intensity of episiotomy pain and wound healing in primiparous women referring to hospitals affiliated with the Gilan university of Medical Sciences in 2014

Protocol summary

Summary

The present study has been conducted to evaluate and compare the effect of cooling gel pads and topical olive oil on the intensity of episiotomy pain and wound healing in primiparous women referring to hospitals affiliated with the Gilan University of Medical Sciences in 2014. This study was randomized clinical trial, without blindness, without placebo. In this study the sample consisted of primiparous women with vaginal delivery and episiotomy referring to hospitals affiliated with the Gilan University of Medical Sciences who have characteristics participants. Inclusion criteria: gestational ages between 37 and 42 weeks; the lack of diseases such as chronic systemic disorders, cardiovascular, respiratory, coagulation disorders and connective tissue, diabetes, anemia, immunosuppressant, hemophilia, malnutrition and psychological disorders; no allergies to topical drugs; no rupture of membranes more than 24 hours; no manual removal of placenta; not taking the first stage of labor (more than 14 hours) and the second stage of labor (more than 2 hours) and the third stage of labor (more than 30 minutes); no problems with cold therapy such as poor circulation and lower pain sensitivity to cold. Exclusion criteria: do not use the cooling gel pads and olive oil properly and as directed; allergic to use olive oil; have a sex in the first 5 days after birth; episiotomy hematoma in the first 24 hours after delivery. In this study, 90 women participated in research project into two groups of cooling gel pads (n =45) and topical olive oil (n =45). After completing the questionnaire (demographic and obstetric and midwifery questionnaire), informed consent and was selected as sample. Then samples were randomly allocated to two groups: cooling gel pad and olive oil. Mothers who use the cooling pad was asked after washing and drying the perineum, covered pads with gauze and mothers used it

for 20 minutes whenever they needed. Mothers who use the olive oil was asked after washing and drying the perineum, olive oil gently placed on the wound 2 times a day for 10 days and then were used the pad after 1-2 minutes. Perineal pain intensity was evaluated using Visual Analogue Scale (VAS) and the wound healing was assessed by the REEDA scoring scale. Then episiotomy healing assessed on 12 hours after delivery, 5 and 10 days postpartum.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409164529N12**

Registration date: **2014-10-30, 1393/08/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-30, 1393/08/08

Registrant information

Name

Nourossadat Kariman

Name of organization / entity

Shaheed Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 3133

Email address

n_kariman@sbbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-07-03, 1393/04/12

Expected recruitment end date

2014-08-21, 1393/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of cooling gel pads and topical olive oil on the intensity of episiotomy pain and wound healing in primiparous women referring to hospitals affiliated with the Gilan university of Medical Sciences in 2014

Public title

The effect of cooling gel pads and topical olive oil on the intensity of episiotomy pain and wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primiparous woman; aged 18 to 35 years; have a vaginal delivery with mediolateral episiotomy without instrumental delivery and without tears; singleton birth with cephalic presentation; was educated; resident in Gilan; gestational ages between 37 to 42 weeks; child weigh between 2500 to 4000 grams; the lack of diseases such as chronic systemic disorders, cardiovascular, respiratory, coagulation disorders and connective tissue, diabetes, anemia, immunosuppressant, hemophilia, malnutrition and psychological disorders; no allergies to topical drugs; not eclampsia and pre-eclampsia; no rupture of membranes more than 24 hours; no addiction; BMI between 19.8-30 kg/m²; no manual removal of placenta; no fetal anomaly or bedfast to the neonatal unit; not taking the first stage of labor (more than 14 hours) and the second stage of labor (more than 2 hours) and the third stage of labor (more than 30 minutes); not problems with cold therapy such as poor circulation and lower pain sensitivity to cold. Exclusion criteria: do not visit for care; do not use the cooling gel pads and olive oil properly and as directed; not interested to continue to participate in the study; allergic to use olive oil; have a sex in the first 5 days after birth; manipulation of the perineum after episiotomy repair; use drugs on wound healing (anticoagulant, antidepressants, antiepileptic, alcohol, immunosuppressant drugs, antibiotics, chemotherapy) during the study; have a episiotomy hematoma in the first 24 hours after delivery.

Age

From 18 years old to 35 years old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study the randomization was based on the consultation with professor of statistics and determine the number of samples, Excel file was available to the researcher that groups code (1= cooling gel pad group, 2= olive oil group) had put it randomly. Consecutive samples were assigned to each group based on their order in the Excel file.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak Street, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Postal code

1985717443

Approval date

2014-08-07, 1393/05/16

Ethics committee reference number

154

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

episiotomy

ICD-10 code

O70.1

ICD-10 code description

Second degree perineal laceration during delivery
Perineal laceration, rupture or tear as in O70.0, also involving: pelvic floor, perineal muscles, vaginal muscles during delivery

Primary outcomes

1

Description

Intensity of episiotomy pain

Timepoint

before intervention, 12 hours, 5 and 10 days postpartum.

Method of measurement

Visual Analogue Scale (VAS)

2

Description

wound healing of episiotomy

Timepoint

before intervention, 12 hours, 5 and 10 days postpartum.

Method of measurement

REEDA scale

Secondary outcomes

empty

Intervention groups

1

Description

Olive oil group: Mothers who use the olive oil was asked after washing and drying the perineum, olive oil gently placed on the wound 2 times a day for 10 days and then were used the pad after 1-2 minutes.

Category

Treatment - Drugs

2

Description

Cooling gel pad group: Mothers who use the cooling pad was asked after washing and drying the perineum, covered pads with gauze and mothers used it for 20 minutes whenever they needed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amini Hospital Langerood

Full name of responsible person

Raheleh Amani

Street address

City

Langerood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Shahid Beheshti

University of Medical Sciences

Full name of responsible person

Dr Afshin Rezghi

Street address

Velenjak Street, Shahid Chamran Highway, Tehran,

Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research Shahid Beheshti 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

School of Nursing and Midwifery of Shahid Beheshti

University of Medical Sciences

Full name of responsible person

Dr Noralsadat Kariman

Position

PHD of Reproductive Health

Other areas of specialty/work

Street address

School of Nursing And Midwifery, Valiasr St, Tehran, Iran

City

Tehran

Postal code

1985717443

Phone

+98 218865536671

Fax

Email

sbnmf@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Rahele Amani

Position

Master student of Midwifery

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

School of Nursing and Midwifery, Valiasr St, Tehran,
Iran

City

Tehran

Postal code

1985717443

Phone

+98 218865536671

Fax**Email**

sbnmf@sbmu.ac.ir

Web page address**Position**

Master Student of Midwifery

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

Tehran

Postal code

4475157871

Phone

+98 218865536671

Fax**Email**

rahilamani94@yahoo.com

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

Person responsible for updating data**Contact****Name of organization / entity**

School of Nursing and Midwifery of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Rahele Amani