

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation the effectiveness of cooling gel pads and ice packs on perineal pain and wound healing after episiotomy

Protocol summary

Summary

Objective: This research was done to evaluate the effectiveness of two cooling devices (gel pad with ice pack)and compare these with no localised treatment (control) on intensity perineal pain after episiotomy in primiparous women inclusion criteria: Iranian (Dewill Mashhad) nationality; primiparous; age 16-35 years; Occiput anterior presentation; Singleton birth; Birth weight (2500-4000 g); Have addresses and telephone number. exclusion criteria:women with any medical disorders or obstetric complications; Fetal anomaly; Stillbirth; Needing neonatal intensive care unit; Retained placenta; Smoking; Consumption of alcohol or continuous drugs; Rupture membrane> 12 hours; Stretch or massage of perineum in pregnancy or during delivery stages; use of lubricant during delivery; second stage of delivery >120 minutes; postpartum haemorrhage; haematoma Population: primiparous women Sample size:121 Intervention : this randomized controlled trial done on 121 primiparous women who were at term and had an episiotomy were randomly recruited to one of three treatment groups(Group 1: no localized cooling; Group2: Ice pack; Group3: Cooling gel pad), .participants used of the treatment in early 4 hr and during 10 days According to their requests. . Time intervention: october 2005 to february 2006 Primary outcome measure:The intensity of episiotomy pain 4hr;1;2;5;10th days Secondary outcome:The wound healing:4hr;1;2;5;10th days and women's satisfaction levels

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107167038N1**

Registration date: **2011-08-11, 1390/05/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-11, 1390/05/20

Registrant information

Name

Shahin Dokht Navvabi-Rigi

Name of organization / entity

Zahedan University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 54 1242 1259

Email address

navabi_rigi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University Of Medical Science

Expected recruitment start date

2005-09-23, 1384/07/01

Expected recruitment end date

2006-01-21, 1384/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of cooling gel pads and ice packs on perineal pain and wound healing after episiotomy

Public title

Effect cold on episiotomy pain and wound healing

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: Iranian (Dewill Mashhad) nationality; primiparous; age 16-35 years; Occiput anterior presentation; Singleton birth; Birth weight (2500-4000 g); Have addresses and telephone number. exclusion criteria: women with any medical disorders or obstetric complications; Fetal anomaly; Stillbirth; Needing neonatal intensive care unit; Retained placenta; Smoking; Consumption of alcohol or continuous drugs; Rupture membrane > 12 hours; Stretch or massage of perineum in pregnancy or during delivery stages; use of lubricant during delivery; second stage of delivery > 120 minutes; postpartum haemorrhage; haematoma

Age

From **16 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **121**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University Of Medical Science

Street address

Mashhad University Of Medical Science; faculty research & IT; Mashhad; Khorasan Razavi

City

Mashhad

Postal code

Approval date

2005-11-30, 1384/09/09

Ethics committee reference number

84225

Health conditions studied

1

Description of health condition studied

Episiotomy Pain

ICD-10 code

070

ICD-10 code description

070

Primary outcomes

1

Description

intensity perineal pain

Timepoint

4 hr; 1,2,5 and 10th days

Method of measurement

NRS(Numeric Rating Scale)

Secondary outcomes

1

Description

wound healing episiotomy

Timepoint

4 hr; 1,2,5 and 10th days

Method of measurement

REEDA scale

2

Description

use of analgesia

Timepoint

during 10 days

Method of measurement

registration number of analgesia in checklist

3

Description

women's satisfaction level

Timepoint

10th day

Method of measurement

numering rating scale

Intervention groups

1

Description

group1: no localized treatment

Category

Treatment - Drugs

2

Description

group2: Ice Pack

Category

Treatment - Devices

3**Description**

group3: cooling gel pad

Category

Treatment - Devices

Recruitment centers1**Recruitment center****Name of recruitment center**

Hazrat-E-Omolbanin Women Hospital;

Full name of responsible person

Dr Monireh Poorjavad

Street address**City**

Mashhad

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Mashhad University Of Medical Science

Full name of responsible person

Zahra Abedian

Street addressmidwifery group ; Nursing and Midwifery School;
Avecina Street; Mashhad University Of Medical
Science; Khorasan Razavi**City**

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Zahedan University of Medical Science

Full name of responsible person

Shahin-Dokht Navvabi-Rigi

Position

Mastery of Midwifery

Other areas of specialty/work**Street address**Post Box Cod 1379, Nursing & Midwifery School,
Meidan Mashahir, Zahedan**City**

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

University of Chester

Full name of responsible person

Mary Steen-Greaves

Position

Professor

Other areas of specialty/work**Street address**Department Health and Social Care ; Riverside
Campus, University of Chester**City**

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Province

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Web page address**Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Shahin-Dokht Navvabi-Rigi

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