Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effectivness 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; primparous; 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 anomally; Stillbirth; Needing neonatal intensive care unit; Retained placenta; Smoking; Consumption of alcohol or continouse 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 primiparouse 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
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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 effectivness 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; primparous; 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 anomally; Stillbirth; Needing neonatal intensive care unit; Retained placenta; Smoking; Consumption of alcohol or continouse 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; faculaty 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 og analgesia in checklist

3

Description
women's satisfation 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 centers

1

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 sources

1

Sponsor
Name of organization / entity
Mashhad University Of Medical Science
Full name of responsible person
Zahra Abedian
Street address
midwifery 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 UniversityoF Medical Science
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Person responsible for scientific inquiries

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Person responsible for updating data

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City
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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