Clinical Trial Protocol
Iranian Registry of Clinical Trials
30 Dec 2020

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; Group 2: Ice pack; Group 3: Cooling gel pad). Participants used the treatment in early 4 hours and during 10 days according to their requests. Time intervention: October 2005 to February 2006. Primary outcome measure: The intensity of episiotomy pain 4 hours; 1, 2, 5, 10th days. Secondary outcome: The wound healing: 4 hours; 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
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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
  2005-11-30, 1384/09/09
- Approval date
- 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 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 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  
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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