Clinical Trial Protocol
Iranian Registry of Clinical Trials
14 Apr 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 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

Name
Shahin Dokht Navvabi-Rigi
Name of organization / entity
Zahedan University Of Medical Science
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+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 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 outcomes

1
Description
intensity perineal pain

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

Method of measurement
NRS(Numeric Rating Scale)

2
Description
wound healing episiotomy

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

Method of measurement
REEDA scale

3
Description
use of analgesia

Timepoint
during 10 days

Method of measurement
registration number og analgesia in checklist

Health conditions studied

1
Description of health condition studied
Episiotomy Pain

ICD-10 code
070

ICD-10 code description
070

Primary outcomes

1
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
eempty
Statistical Analysis Plan
eempty
Informed Consent Form
eempty
Clinical Study Report