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 continous 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

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; 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 anomaly; 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

Sample size
Target sample size: 121

Randomization (investigator's opinion)
Randomized

Blinding (investigator's opinion)
Not blinded

Placebo
Not used

Assignment
Parallel

Secondary design features
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Mashhad University Of Medical Science
Street address
Mashhad University Of Medical Science; facultay research & IT; Mashhad; Khorasan Razavi
City
Mashhad
Postal code
84225
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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact
Name of organization / entity
Zahedan UniversityoF 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,
Meydan Mashahir, Zahedan
City
Zahedan
Postal code
+98 54 1242 1259
Phone
Fax
Email
shahinnavabi@yahoo.com
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
Chester
Province
Chester
Postal code
Phone
01244 512284
Fax
Email
m.steen@chester.ac.uk <m.steen@chester.ac.uk>
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