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 4 hr; 1, 2, 5, 10th days. Secondary outcome: The wound healing: 4 hr; 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; 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

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

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

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<tr>
<td>Name of recruitment center</td>
<td>Hazrat-E-Omolbanin Women Hospital;</td>
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<tr>
<td>Full name of responsible person</td>
<td>Dr Monireh Poorjavad</td>
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<td>Street address</td>
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<td>Mashhad</td>
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## Sponsors / Funding sources

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<td>Name of organization / entity</td>
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<tr>
<td>Full name of responsible person</td>
<td>Zahra Abedian</td>
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<td>Street address</td>
<td>midwifery group ; Nursing and Midwifery School; Avecina Street; Mashhad University Of Medical Science; Khorasan Razavi</td>
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## Person responsible for general inquiries

| Name of organization / entity | Zohedan 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 | Zahedan |

## Person responsible for scientific inquiries

| 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 | 01244 512284 |
| Phone | |
| Fax | |
| Email | m.steen@chester.ac.uk <m.steen@chester.ac.uk> |

## Person responsible for updating data

| Name of organization / entity | Zohedan University Of Medical Science |
| Full name of responsible person | Shahin-Dokht Navvabi-Rigi |
| Position | |
| Other areas of specialty/work | |
| Street address | |
| City | |
| Postal code | |
| Phone | |
| Fax | |
| Email | |

## Sharing plan

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