Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison Apotel and suppositories diclofenac on pain relief after cesarean section among primiparous women

Protocol summary

Summary

One of the major problems is pain after surgery. This study aimed to compare the analgesic effect of diclofenac suppository and Apotel on pain after cesarean section in nulliparous women. This study is single-blind clinical trial. All qualified nulliparous women with singleton pregnant and 38 to 42 weeks gestational age will be selected by convenience sampling.Then, using random blocks will be put in two groups of Apotel and diclofenac suppository. One hour and thirty minutes after spinal anesthesia and before Back pain after surgery in both groups were given 50 mg of pethidine vial. And then to a group of mothers expressed the need for analgesic 100 mg suppositories diclofenac And the other group vial Apote (1000 mg) will be Infusion by the researcher assistant. Pain intensity will be assessed before intervention by the McGill Pain Questionnaire short form and then within 24 hours, 2 times the distance of 6 to 8 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092513336N2**
Registration date: **2016-04-22, 1395/02/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-22, 1395/02/03

Registrant information

Name

Maryam Aradmehr

Name of organization / entity

School of Nursing and Midwifery Mashhad

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Apotel and suppositories diclofenac on pain relief after cesarean section among primiparous women

Public title

Comparison Apotel and suppositories diclofenac on pain relief after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: minimum education subjects as reading and writing, lives with his wife, a singleton pregnancy, gestational age 38 to 42 weeks, primiparous women, healthy baby and the first minute Apgar score 7-10, the same method cesarean delivery and a cross-section (skin and uterus), mothers with vital signs are favorable. Exclusion criteria: The presence of unusual complication of surgery (bladder trauma or other injury during surgery), preoperative fever, Smoking and drug

addiction, hysterectomy Associated with cesarean, suffering from medical disorders (diabetes, hypertension, heart disease and vascular, renal, pulmonary, gastrointestinal, thyroid, immune disorders, infectious, psychiatric, metabolic disorders, electrolyte and irritable bowel syndrome), sensitivity to paracetamol, liver and kidney function decline, chronic alcoholism, chronic malnutrition or dehydration, taking probenecid or Sylasyd year or drugs are enzyme induction.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Sciences

Street address
Khorasan Razavi,Mashhad,Mashhad University of Medical Sciences

City
Mashhad

Postal code

Approval date
2015-07-30, 1394/05/08

Ethics committee reference number
930562

Health conditions studied

1

Description of health condition studied
Pain after cesarean

ICD-10 code
O82.9

ICD-10 code description
Delivery by caesarean section, unspecified

Primary outcomes

1

Description
pain of cesarean section

Timepoint
before the intervention until the 24 hours after intervention

Method of measurement
McGill Pain Questionnaire short

Secondary outcomes

1

Description
Physical activity and psychosocial

Timepoint
12 and 24 hours after cesarean section

Method of measurement
Interview form Pain interference with physical activity and psychosocial

Intervention groups

1

Description
In the intervention group, One hour and thirty minutes after spinal anesthesia and before Back pain after surgery were given 50 mg of pethidine vial. And then expressed the need for analgesic vial Apotel (1000 mg) to 4 times a day will be Infusion by the researcher assistant. and there will be at least a 4-hour interval between two consecutive injections. will be recorded amount Apotel used.

Category
Treatment - Drugs

2

Description
In the intervention group, One hour and thirty minutes after spinal anesthesia and before Back pain after surgery were given 50 mg of pethidine vial. And then expressed the need for analgesic vial Apotel (1000 mg) to 4 times a day will be Infusion by the researcher assistant. and there will be at least a 4-hour interval between two consecutive injections. will be recorded amount Apotel used.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital, Mashhad University ofMedical Sciences

Full name of responsible person
maryam aradmehr, Msc of Midwifery School of Nursing and Midwifery Mashhad

Street address
Khorasan Razavi,Mashhad,Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Council of Mashhad University of Medical Sciences

Full name of responsible person
Dr.tafaghodi

Street address
Khorasan Razavi, Mashhad University Avenue, Building Qureshi

City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Council of Mashhad University of Medical Sciences

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
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Aradmehr

Position
MSc of Midwifery

Other areas of specialty/work

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Azhari sedigheh

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Person responsible for updating data

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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