

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)

Phone

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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 of Medical Sciences

Full name of responsible person

Maryam Aradmehr, MSc of Midwifery School of Nursing and Midwifery Mashhad

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Web page address

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

Street address

Khorasan Razavi, Mashhad, intersection, Doktora Intersection, School of Nursing and Midwifery,

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Mashhad

Full name of responsible person

Azhari sedigheh

Position

Master of Midwifery, Faculty of Nursing and Midwifery

Other areas of specialty/work

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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