Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of analgesic effect of Diclofenac, Indomethacin. Naproxen and Acetaminophen suppository after cesarean section

Protocol summary

Summary

In this clinical trial we are aiming at finding the best way of controlling pain after cesarean section. This is a triple blind study on 120 pregnant women referred to Afzalipour hospital for cesarean section. Exclusion criteria include: patient's cancellation of entering into this study, bleeding, time consuming surgery, unexpected events, severe pain which needs additional analgesics. Inclusion criteria are: age 20-45 year, weight 60-80kg, primi gravid, no sensitivity or special illness. Visual analogue scale will be taught to all patients who are subjected to the study and then general anesthesia with Thiopental and Succinyl will be given to them. During anesthesia Atracurium and Fentanyl will be administered and finally the anesthesia will be kept on Isoflurane and N2O. The patients will be divided into groups postoperatively. Interventions include administration of suppositories of Indometacine 100mg in group I, Naproxen 500mg in group II, Acetaminophen 325mg in group III, and Diclofenac 100mg in group IV, administering rectally when the patient has pain. At the time of arriving a trained nurse who is blind to administered medicine watches and evaluates vital signs and pain, by means of Visual Analogue Scale. After administration of suppository, 15 minutes and one hour after administration, vital signs and pain will be evaluated again. Then information will be recorded in forms and data of any of four groups import in SPSS as codes and analysis will be done. Analyzer will be blind to groups. The blindness will be opened by the manager and data will be interpreted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205139585N1**
Registration date: **2012-12-18, 1391/09/28**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2012-12-18, 1391/09/28

Registrant information

Name
Ali Barkhori
Name of organization / entity
Kerman University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 34 1211 5803
Email address
a_barkhori@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of Diclofenac, Indomethacin. Naproxen and Acetaminophen suppository after cesarean section

Public title

Comparison of analgesic effect of s̊uppositories after cesarean section

Purpose
Treatment
Inclusion/Exclusion criteria
The inclusion criteria: primi gravid, term fetus, 37 week or more pregnancy and patients with 20 to 45 years old and weight of 60 to 80 kg indicated for elective surgery. The exclusion criteria: History of allergy to NSAIDs , Bronchial asthma , History of abdominal surgery, Opium addiction , Previous cesarean section, Hemorrhoid , Proctitis , gestational hypertension, preeclampsia, Bleeding tendency, Gastric ingestion ulcers, liver and kidney disease , Patients that refuse to follow the study or severity of their pain needs use of opioid or other analgesics
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Vice chancellor for research, Kerman University of Medical Science
Street address
Shafa Street , Shafa Cross Road
City
Kerman
Postal code
Approval date
2011-02-19, 1389/11/30
Ethics committee reference number
91/60/ک

Health conditions studied

1

Description of health condition studied
Pain after cesarean section
ICD-10 code
R10.2
ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description
Pain severity
Timepoint
after drug administration, 15 minutes after drug administration, and an hour later.
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Indomethacin intervention: A trained personnel without knowing the name of the medication checks the patient's vital signs on arrival in the recovery room, and then a 100 mg Indomethacin suppository (made by Caspian Tamin with brand name of INDIC) is administered as a stat dose. Patient's pain is evaluated by Visual Analogue Scale after drug administration, 15 minutes after drug administration, and an hour later.
Category
Treatment - Drugs

2

Description
Naproxen Intervention: A trained personnel without knowing the name of the medication checks the patient's vital signs on arrival in the recovery room, and then a 500 mg Naproxen suppository (made by Abureyhan Company) is administered as a stat dose. Patient's pain is evaluated by Visual Analogue Scale after drug administration, 15 minutes after drug administration, and an hour later.
Category
Treatment - Drugs

3

Description
Diclofenac intervention: a trained personnel without knowing the name of the medication checks the patient's vital signs on arrival in the recovery room, and then a 100 mg Diclofenac suppository (made by Mahandaroo Company) is administered as a stat dose. Patient's pain

is evaluated by Visual Analogue Scale after drug administration, 15 minutes after drug administration, and an hour later.

Category

Treatment - Drugs

4

Description

Acetaminophen intervention: a trained personnel without knowing the name of the medication checks the patient's vital signs on arrival in the recovery room, and then a 325mg Acetaminophen suppository (made by Abureyhan Company) is administered as a stat dose. Patient's pain is evaluated by Visual Analogue Scale after drug administration, 15 minutes after drug administration, and an hour later.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital of Kerman

Full name of responsible person

Matin Hashemi

Street address

Emam Khomeini Highway Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Hasani

Street address

Ebn Sina Street Tahmasb Abad Cross Road

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Matin Hashemi Shadmehri

Position

Resident of Anesthesiology

Other areas of specialty/work

Street address

Afzalipor Hospital Emam Khomeini Highway

City

Kerman

Postal code

7618113467

Phone

+98 34 1282 0361

Fax

+98 34 1211 5803

Email

matinhashemi60@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Ali Barkhori

Position

Assistant Professor

Other areas of specialty/work

Street address

Shafa Street. Shafa Hospital

City

Kerman

Postal code

7618751151

Phone

+98 34 1211 5806

Fax

+98 34 1211 5803

Email

a_barkhori@kmu.ac.ir

Web page address

shafah.kmu.ac .ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Science

Full name of responsible person

Dr Mohamad Reza Dourodian

Position

Assistant Professor

Other areas of specialty/work

Street address

Shafa Street. Shafa Hospital

City

Kerman

Postal code

7618113467

Phone

+98 34 1222 1600

Fax

+98 34 1222 1600

Email

Kmu.ac.ir@yahoo.com

Web page address

www.kmu.ac.ir

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