

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trials of Comparison the effect of two methods, patient controlled analgesia and non steroidal anti inflammatory drugs after elective cesarean section

Protocol summary

Summary

Clinical trials of comparison the effect of two methods, patient controlled analgesia and non steroidal anti inflammatory drugs after elective cesarean section; Objectives: Comparison the effect of two methods, patient controlled analgesia and non steroidal anti inflammatory drugs after elective cesarean section; Design: This clinical trial study, using purposive sampling method, was conducted on 100 elective cesarean section patients referred to Sadjad Hospital in Kermanshah city in 2014; Inclusion criteria: age between 20 to 35, no history of cesarean surgery, not suffering from chronic pain, BMI less than 30, no sensitivity to opioids drugs, chronic diseases and patient's written consent; Exclusion criteria: a history of addiction to opioids, history of liver and kidney diseases, the existence of mental illness verified by a physician and lack of interest or withdrawal during the conduction of the study; Intervention: Intervention group: namely injection by pump, analgesic pump contains 20 milligrams Morphine, 16 milligrams Dexamethasone, 8 milligrams Ondansetron, 10 milligrams Chlorpheniramine, 200 milligrams Apotel and 2 milligrams which is diluted with normal saline to a volume of 100 cc. were injected by the patients at injection speeds of 8cc. Control group: whenever there analgesics were needed 100 milligrams Diclofenac was injected intramuscularly or Diclofenac suppository was used in turn; Main outcome measures variables: Postoperative pain

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014091619197N1**
Registration date: **2014-10-29, 1393/08/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-29, 1393/08/07

Registrant information

Name

Majid Ahmadi

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3726 0606

Email address

majid.ahmadi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-08-28, 1393/06/06

Expected recruitment end date

2014-09-28, 1393/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials of Comparison the effect of two methods, patient controlled analgesia and non steroidal anti inflammatory drugs after elective cesarean section

Public title

Clinical trials of Comparison the effect of two methods, patient controlled analgesia and non steroidal anti inflammatory drugs after elective cesarean section

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: age between 20 to 35, no history of cesarean surgery, not suffering from chronic pain, BMI less than 30, no sensitivity to opioids drugs, chronic diseases and patient's written consent. Exclusion criteria: a history of addiction to opioids, history of liver and kidney diseases, the existence of mental illness verified by a physician and lack of interest or withdrawal during the conduction of the study.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The design of this study has not been randomly.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sadjad hospital

Street address

Bahar street, Kermanshah

City

Kermanshah

Postal code

-

Approval date

2014-08-26, 1393/06/04

Ethics committee reference number

SA-FC-00-0064

Health conditions studied

1

Description of health condition studied

postoperative pain

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

pain intensity

Timepoint

every 6 hours after intervention

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, namely injection by pump, analgesic pump contains 20 milligrams Morphine, which is diluted with normal saline to a volume of 100 cc. were injected by the patients at injection speeds of 8cc. They were instructed to press the infusion button to receive more medication as soon as feeling of pain started. By pressing the button, each time patient receives 0.5 cc serum-containing analgesics.

Category

Treatment - Drugs

2

Description

In the control group, whenever there analgesics were needed 100 milligrams Diclofenac was injected intramuscularly or Diclofenac suppository was used in turn (according to the available protocols).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadjad hospital

Full name of responsible person

Majid Ahmadi

Street address

Bahar street, Kermanshah
City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Majid Ahmadi

Street address

Bahar street, Kermanshah

City

Kermanshah

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Investigator

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

Sadjad hospital

Full name of responsible person

Majid Ahmadi

Position

postgraduate student- responsible for OR

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Majid Ahmadi

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postgraduate student

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Sadjad hospital

Full name of responsible person

Majid Ahmadi

Position

postgraduate student- responsible for OR

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