

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of adding dexmedetomidine with fentanyl, to acetaminophen in intravenous patient controlled analgesia (PCA), for pain after Caesarean section

Protocol summary

Summary

The purpose of this research is survey of the effectiveness of intravenous infusion pump combined with(dexmedetomidine and acetaminophen) compared with(fentanyl and acetaminophen) for postoperative pain control in patients who have undergone cesarean section. Inclusion criteria: Parturient with age between 20 and 38 years who come to Rasool e Akram hospital and cesarean under neuroaxial(spinal or epidural) anesthesia and Exclusion criteria: Dissatisfaction and history of opioid analgesic use or tranquilliser use.60 individuals alternatively allocate to Group A and Group B .In Group A PCIA protocol consisted of 2g Acetaminophen and fentanyl (0.3 mic.g./kg/min for24h)diluted into 100 ml with physiological saline and administered at a continuous infusion rate of 4 ml/h. In Group B PCIA protocol consisted of 2g Acetaminophen and dexmedetomidine(0.15 mic.g./kg/h for24h)diluted into 100 ml with physiological saline and administered at a continuous infusion rate of 4 ml/h.Then Visual Analogue Scale and vital signs evaluate after 1, 6, 12 , 24 h for the first 24 h. postoperatively.All patients receive 25mg pethidine for postoperative analgesia if VAS was more than 3. Bradycardia define HR(Heart Rate) more than 20% decline from the baseline and Hypotension define MBP(Mean Blood Pressure) more than 20% decline from the baseline. Bradycardia was treated with intravenous Atropine(0.02mg/kg) and Hypotension was treated with intravenous Ephedrine(0.1mg/kg). Side effects and satisfaction is evaluated for 24 h after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503117984N23**
Registration date: **2016-03-09, 1394/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-09, 1394/12/19

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 5758

Email address

farnadimani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of IRAN
University of Medical Sciences

Expected recruitment start date

2016-01-30, 1394/11/10

Expected recruitment end date

2016-04-24, 1395/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of adding dexmedetomidine with fentanyl, to acetaminophen in intravenous patient controlled

analgesia (PCA), for pain after Caesarean section

Public title

The effectiveness of intravenous infusion pump combined with (dexmedetomidine and acetaminophen) compared with (fentanyl and acetaminophen) for postoperative pain control in patients who have undergone cesarean section.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Parturient with age between 20 and 38 years who come to Rasool e Akram hospital; Parturients undergoing elective caesarean delivery; American Society of Anesthesiologists (ASA) physical statuses grade I and II; Parturient undergoing neuroaxial(spinal or epidural) anesthesia. Exclusion criteria: Dissatisfaction;Emergency caesarean delivery; American Society of Anesthesiologists (ASA) physical statuses grade more than II; Parturient with age less than 20 and more than 38 years old; Parturient undergoing general anesthesia;A history of opioid analgesic use or tranquilliser use.

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Tehran

City

Tehran

Postal code

Approval date

2016-03-01, 1394/12/11

Ethics committee reference number

IR.IUMS.REC.1394.26792

Health conditions studied

1

Description of health condition studied

postoperative analgesia

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

pain

Timepoint

hours: 1-6-12-24

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

parturient satisfaction

Timepoint

Hour 24

Method of measurement

parturient expression

2

Description

Hypotension

Timepoint

Hours 1 - 6 - 12 - 24

Method of measurement

Manometer

3

Description

Bradycardia

Timepoint

Hours 1 - 6 - 12 - 24

Method of measurement

Timer

4

Description

nausea and vomiting

Timepoint

Hours 1 - 6 - 12 - 24

Method of measurement

parturient expression

Tehran - Hemmat Expressway - Iran University of Medical Sciences

Intervention groups

1

Description

In first group PCIA protocol consisted of 2g Acetaminophen and fentanyl (0.3 mic.g./kg/min for 24h) diluted into 100 ml with physiological saline and administered at a continuous infusion rate of 4 ml/h.

Category

Treatment - Drugs

2

Description

In second group PCIA protocol consisted of 2g Acetaminophen and dexmedetomidine (0.15 mic.g./kg/h for 24h) diluted into 100 ml with physiological saline and administered at a continuous infusion rate of 4 ml/h.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran- Rasool e Akram Hospital - General operating room

Full name of responsible person

Shakeri - Asadollah

Street address

Tehran- Rasool e Akram Hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Tehran -Rasool e Akram Hospital-General Operating Room and Gynecology and obstetric ward

Full name of responsible person

Shakeri - Asadollah

Street address

Tehran -Rasool e Akram Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mousavi

Street address

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Science

Full name of responsible person

Shakeri Asadollah

Position

Pain Assistant Fellowship

Other areas of specialty/work

Street address

Tehran -Rasool e Akram Hospital- Pain Operating Room

City

Tehran

Postal code

Phone

+216 4352107

Fax

Email

ashakeri123@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Shakeri Asadollah

Position

Pain Assistant Fellowship

Other areas of specialty/work

Street address

Tehran -Rasool e Akram Hospital- Pain Operating Room

City

Tehran

Postal code

Phone

+98 21 6435 2107

Fax

Email

ashakeri123@yahoo.com

Web page address

Phone

+98 21 6435 2107

Fax

Email

ashakeri123@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Shakeri Asadollah

Position

Pain Assistant Fellowship

Other areas of specialty/work

Street address

Tehran -Rasool e Akram Hospital- Pain Operating Room

City

Tehran

Postal code

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