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
Hypotention
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

Intervention groups

1

Description
In first group 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.
Category
Treatment - Drugs

2

Description
In second group 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.
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 obestetric 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
Tehran - Hemmat Expressway - Iran University of Medical Sciences
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

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
Phone
+98 21 6435 2107
Fax
Email
ashakeri123@yahoo.com
Web page address

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