Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of analgesic effect of intravenous pump dexmedetomidine with paracetamol and ketorolac with paracetamol on postoperative pain after cesarean section

Protocol summary

Study aim

The comparison of analgesic effect of intravenous pump of dexmedetomidine with paracetamol and ketorolac with paracetamol on postoperative pain after cesarean section under spinal anesthesia

Design

This is a clinical trial study with parallel groups, double-blinded randomized, will be conducted on 60 women undergoing cesarean section with spinal anesthesia. Assignment of patients to the study groups will be done by random-numbers table and using computer.

Settings and conduct

From pregnant women candidate for cesarean section with spinal anesthesia referring to Imam Khomeini hospital, Ahvaz, total of 60 patients will be selected and randomly divided into 2 groups. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

Participants/Inclusion and exclusion criteria

- Inclusion criteria: age between 18 to 40 years, ASA Class I and II, Candidate for elective cesarean section, No drug allergies to dexmedetomidine, ketorolac and paracetamol, stable hemodynamics, consent to participate in the study; Exclusion criteria: history of asthma, history of bleeding or gastrointestinal ulcer, severe liver disease

Intervention groups

In the first group, Paracetamol 1 g and Dexmedetomidine 0.2 µg/kg soluted in 100 cc normal saline will be injected via analgesic pump at a rate of 4 mL/h, after surgery and before the patient entry to recovery. In the second group, Paracetamol 1 g and ketorolac 0.5 ml/kg soluted in 100 cc normal saline will be injected via analgesic pump at a rate of 4 mL/h, after surgery and before the patient entry to recovery.

Main outcome variables

Pain severity, Hemodynamic changes including systolic blood pressure, diastolic blood pressure, Heart rate, anxiety and presence of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191025045237N1**
Registration date: **2020-12-19, 1399/09/29**
Registration timing: **prospective**

Last update: **2020-12-19, 1399/09/29**
Update count: **0**

Registration date

2020-12-19, 1399/09/29

Registrant information

Name

Hamid Hajilari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 0168

Email address

drhh1353@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of analgesic effect of intravenous pump dexmedetomidine with paracetamol and ketorolac with paracetamol on postoperative pain after cesarean section

Public title
The effect of intravenous pump dexmedetomidine with paracetamol and ketorolac with paracetamol on pain after cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 40 years ASA Class I and II Candidate for elective cesarean section No drug allergies to dexmedetomidine, ketorolac and paracetamol Stable hemodynamics Consent to participate in the study
Exclusion criteria:
history of asthma history of bleeding or gastrointestinal ulcer severe liver disease
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random-numbers table and using computer, and on this basis patients will be included in one of the two treatment groups before starting intervention. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Intervention (receiving Dexmedetomidine or Ketorolac with Paracetamol) and patient evaluation will be carried out by a physician who is blinded to both treatment groups. Also patients and statistical analyzer will not know about patient grouping.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2020-02-22, 1398/12/03
Ethics committee reference number
IR.AJUMS.REC.1398.926

Health conditions studied

1

Description of health condition studied
pain after cesarean section
ICD-10 code
G89.1
ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description
Severity of Pain
Timepoint
The time of 2, 4, 8, 12 and 24 hours after the surgery
Method of measurement
Visual analog scale (VAS)

2

Description
Hemodynamics changes (Systolic and diastolic blood pressure, heart rate)
Timepoint
The time of 2, 4, 8, 12 and 24 hours after the surgery
Method of measurement
Mercury barometer

Secondary outcomes

1

Description
nausea and vomiting
Timepoint
The time of 2, 4, 8, 12 and 24 hours after the surgery
Method of measurement
presence of nausea and vomiting based on direct observation and patients report

2

Description
Intensity of patients' anxiety
Timepoint
The time of 2, 4, 8, 12 and 24 hours after the surgery
Method of measurement
Ramsey sedate score (1-6)

Intervention groups

1

Description
Intervention group: Paracetamol 1 g (Exir CO., Iran) and Dexmedetomidine 0.2 µg/kg (Abureihan CO., Iran) soluted in 100 cc normal saline will be injected via analgesic pump (Kanak Technology Co.) at a rate of 4 mL/h, after surgery and before the patient entry to recovery.
Category
Prevention

2

Description
Intervention group: Paracetamol 1 g (Exir CO., Iran) and ketorolac 0.5 ml/kg (Exir CO., Iran) soluted in 100 cc normal saline will be injected via analgesic pump at a rate of 4 mL/h, after surgery and before the patient entry to recovery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Hamid Hajilari
Street address
Imam Khomeini Hospital, Azadegan St.
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drhh1353@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
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Email
badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Hamid Hajilari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Imam khomeini hospital ,Ahvaz city

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available