Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparing of programmed intermittent epidural bolus (PIEB) with continuous epidural infusion (CEI) for labor analgesia in patients receiving epidural dexmedetomidine and Rupivacaine

Protocol summary

Study aim
Comparing of programmed intermittent epidural bolus with continuous epidural infusion in labor analgesia with solution of Dexmedetomidine and Rupivacaine

Design
Clinical trial, with parallel groups, double-blind, randomized, phase 2-3 on 60 patients. In order to randomize, the block randomization method will be used.

Settings and conduct
In Akbarabadi Hospital, women with a gestational age greater than or equal to 37 weeks will be enrolled to the study. Patients will be randomly divided into 2 groups based on Blocks with size 6. The sample size for each study group is 30. A total of 60 patients will be examined. Patients، surgeons and data analyzer will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Term women with gestational age 37 weeks or more, Cervical dilation Larger than 4 cm, Spontaneous or induced labor pain, Applying for epidural analgesia, Weight 55 to 85 kg. Exclusion criteria: History of sever cardiovascular diseases, Contraindication of epidural analgesia, Patients that are candidate for cesarean section (multiple pregnancy , gestational age more than 37 weeks, preeclampsia , etc), Patient discontent, Opium addiction, Height less than 150 cm

Intervention groups
In the first intervention group: with programmed intermittent epidural bolus, bolus dose of 8cc of the solution will be administered every 60 minutes regularly. In the second intervention group: with continuous epidural infusion, infusion of 8 cc/hr of the solution consumption as maintenance after loading dose will be administered continuously by an infusion pomp.

Main outcome variables
Degree of reduced labor pain and pain relief maternal satisfaction; Total analgesic solution consumption; Apgar score; Side effects and hemodynamic changes

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210405050851N1**
Registration date: **2021-10-30, 1400/08/08**
Registration timing: **prospective**

Last update: **2021-10-30, 1400/08/08**
Update count: **0**

Registration date
2021-10-30, 1400/08/08

Registrant information
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-06, 1400/08/15
Expected recruitment end date
2022-02-19, 1400/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing of programmed intermittent epidural bolus (PIEB) with continuous epidural infusion (CEI) for labor analgesia in patients receiving epidural dexmedetomidine and Rupivacaine

Public title
Comparing of programmed intermittent epidural bolus with continuous epidural infusion for labor analgesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Term woman with gestational age 37 weeks or more Cervical dilation Larger than 4 cm Spontaneous or induced labor pain Applying for epidural analgesia Weight 55 to 85 kg

Exclusion criteria:
Patients with past medical history of sever cardiovascular diseases and bradycardia Contraindication of epidural analgesia Patients that are candidate for cesarean section (multiple pregnancy , gestational age more than 37 weeks, preeclampsia , etc) Patient discontent Opium addiction Height less than 150 cm

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2-3

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 randomly assigned to tree groups by using a random number table. In order to randomize, a random block method will be used. For this purpose, we formed blocks of size 6. In each block, 3 individuals will be in first intervention group and 3 will be in second intervention group. A total of 10 blocks will be considered for the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Surgeons and patients will be kept blind and unaware of the type of labor analgesia . Patients will be aware that they will be randomly assigned to one of two treatment groups, but will be unaware of which analgesic method will be provided in that group. Patients will be assigned to one of two groups using random number tables. The surgeon also knows that patients will be anesthetized in two different ways, but will not know which procedure will be performed for each patient. The data collection officer, analyst and outcome assessor will collect and analyze information based on groups 1 and 2 and will not be aware of the type of type of analgesia presented in the groups. They will be kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Science

Street address
Iran University of Medical Sciences, Hemmat Highway

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Tehran

Province
Tehran

Postal code
1449614535

Approval date
2020-09-19, 1399/06/29

Ethics committee reference number
IR.IUMS.FMD.REC.1399.397

Health conditions studied

1

Description of health condition studied
Epidural labor analgesia

ICD-10 code
O74.6

ICD-10 code description
Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description
Maternal satisfaction of labor analgesia

Timepoint
At the end of labor

Method of measurement
Visual analogue scale

2

Description
Total dose of Dexmedetomidine using in the end of labor

Timepoint

At the end of labor

Method of measurement

Based on checklist - in milliliters

3

Description

Total dose of Rupivacain using in the end of labor

Timepoint

At the end of labor

Method of measurement

Based on checklist - in milliliters

Secondary outcomes

1

Description

New born Infant Apgar score

Timepoint

In the first and fifth minute after fetal delivery

Method of measurement

Apgar score

2

Description

Infant Arterial Blood Gas

Timepoint

Five minutes after fetal delivery

Method of measurement

Umbilical cord arterial blood

3

Description

Incidence rate of instrumental delivery

Timepoint

The last stage of delivery

Method of measurement

Record in the end of labor

4

Description

Duration of delivery

Timepoint

Duration of delivery from the time of patient entrance in the labor until the time of fetal delivery

Method of measurement

Based on checklist - minute unit

5

Description

Side effects including nausea, vomiting, itching, decrease blood pressure, bradycardia

Timepoint

From the loading dose of epidural analgesia every hour till the end of labor

Method of measurement

Patient's sign and symptoms and record in the checklist

6

Description

Incidence rate of motor block

Timepoint

From the beginning of Epidural analgesia every hour till the end of labor

Method of measurement

Bromage score (0- 1- 2- 3)

Intervention groups

1

Description

Intervention group 1: Term women with gestational age 37 weeks or more who have entrance condition to the study, amount of 3cc test dose of Dexmedetomidine 0.5µg/ml and Rupivacain %0.1 will be administered and after 5 minutes, amount of 8cc from the same solution as loading dose will be administered. then in the group programmed intermittent epidural bolus, bolus dose of 8cc of the solution will be administered every 60 minutes regularly.

Category

Treatment - Drugs

2

Description

Intervention group 2: Term women with gestational age 37 weeks or more who have entrance condition to the study, amount of 3cc test dose of Dexmedetomidine 0.5µg/ml and Rupivacain %0.1 will be administered and after 5 minutes, amount of 8cc from the same solution as loading dose will be administered. in the continuous epidural infusion group, infusion of 8 cc/hr of the solution consumption as maintenance after loading dose will be administered continuously by an infusion pomp.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi hospital

Full name of responsible person

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Sponsors / Funding sources

1

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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
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

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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available