

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 Ropivacaine

Protocol summary

Study aim

Comparing of programmed intermittent epidural bolus with continuous epidural infusion in labor analgesia with solution of Dexmedetomidine and Ropivacaine

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 severe 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 pump.

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

Name

golnoosh khosravian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 4717

Email address

desdemonawsh@yahoo.com

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 Ropivacaine

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 pump.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi hospital

Full name of responsible person

Golnoosh Khosravian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Golnoosh Khosravian

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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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