Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of bolus epidural injection and continuous epidural infusion of lidocaine 1% on pain, normal delivery and motor function in patients with epidural analgesia

Protocol summary

Study aim

Comparison of bolus injection and continuous epidural infusion of lidocaine 1% on pain, normal delivery and motor function in patients with epidural analgesia

Design

50 patients are entered into a randomized, single-blind, phase 2-3 clinical trial and randomly assigned into 4 blocks and entered into one of the two groups of continuous and bolus epidural analgesia.

Settings and conduct

After placing catheter in epidural space, eligible patients in the Fatemieh Hospital of Hamedan received 10 ml of lidocaine 1% in epidural space and randomly placed in one of two groups of bolus or continuous and two types of analgesia is given . However, evaluator and patient do not know how to drug inject.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients aged 16 to 45; First pregnancy; Failure to receive previous analgesic; Vertex presentation; ASA class 1 and 2 Exclusion criteria: Epidural anesthetic contraindications (coagulation problems, hypovolemia, local infection, high ICP and anemia); ASA class 3 and 4; Poor collaboration in epidural analgesia; Failure to cooperate in answering questionnaire questions

Intervention groups

After placing catheter in epidural space, in both groups, 10 ml lidocaine 1% plus 1 ml of sufentanil is injected through the catheter into epidural space by anesthetist. Then, in bolus group, every 1 hour, 10 ml lidocaine 1% is injected regularly and in continuous group, lidocaine 1% is infused through a continuous infusion pump at a rate of 10 ml / h in epidural space until delivery.

Main outcome variables

Both groups are evaluated for VAS of pain and vital signs every 10 minutes. Also, total dose of lidocaine; nausea and vomiting; delivery progress; level of sensory and motor block and patient's satisfaction with analgesia during delivery is examined by anesthetic nurse and is recorded in questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N9**
Registration date: **2018-08-24, 1397/06/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-24, 1397/06/02**
Update count: **0**

Registration date

2018-08-24, 1397/06/02

Registrant information

Name

Nahid Manuchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

Email address

manouchehrian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of bolus epidural injection and continuous epidural infusion of lidocaine 1% on pain, normal delivery and motor function in patients with epidural analgesia

Public title

Epidural effects on labor pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with first pregnancy Aged 16 to 45 Failure to receive previous analgesic Vertex presentation ASA physical status class 1 and 2

Exclusion criteria:

Epidural anesthesia contraindications (coagulation problems, hypovolemia, localized infections, high ICP and anemia) patients with ASA physical status class 3 and 4 presence of lesions and skin infections on the lumbar and back of the patient patients with poor cooperation in performing of epidural analgesia patients who did not cooperate to answer the questionnaire questions).

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the randomization method is used as a 4-block block. In this way, according to the sample size, 13 blocks of four are identified, and in each of these four blocks, two of each group will be written in the form of letters A or B. This means that two A and two B are written in each block, although the order of the writing of the four letters A and B will be different in each block. The periodic numbers table will then be used to determine the order of block selection.

Blinding (investigator's opinion)

Single blinded

Blinding description

After determining the epidural space and placing the catheter in the epidural space, in both groups, the 10 ml lidocaine 1% plus 1 ml of sufentanil is injected through the epidural catheter placed behind the patient. Then, in the bolus group, every one hour, 10 ml lidocaine 1% through an epidural catheter is bolusly injected into the epidural space by anesthesiologist regularly until delivery.In the continuous infusion group, lidocaine 1% is infused through a continuous infusion pump at a rate of 10 ml / h into the epidural space until delivery. The questionnaire is then completed by an anesthetist nurse. In this study, the evaluator and the patient do not know the type of drug administration as bolus and continuous infusion.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Mahdie Street, Hamadan University of Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.UMSHA.REC.1397.222

Health conditions studied

1

Description of health condition studied

Vaginal delivery under epidural analgesia

ICD-10 code

074.6

ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description

Labor pain

Timepoint

Before and after epidural analgesia and minutes 10, 20, 30, 40, 50, 60 after epidural analgesia and the onset and end of the second stage of labor

Method of measurement

Using a Visual Analogue Scale, that patient marks his pain on a 10-cm ruler.

2

Description

Progress of labor

Timepoint

During labor

Method of measurement

Measurement of the duration of the first and second stages of labor

3

Description

Motor function

Timepoint

Before and after epidural analgesia and minutes 10, 20, 30, 40, 50, 60 after epidural analgesia and the onset and end of the second stage of labor

Method of measurement

Using Bromage Score

Secondary outcomes

1

Description

Systolic Blood Pressure

Timepoint

Before and after epidural analgesia and minutes 10, 20, 30, 40, 50, 60 after epidural analgesia and the onset and end of the second stage of labor

Method of measurement

Noninvasive blood pressure monitoring

2

Description

Diastolic Blood Pressure

Timepoint

Before and after epidural analgesia and minutes 10, 20, 30, 40, 50, 60 after epidural analgesia and the onset and end of the second stage of labor

Method of measurement

Noninvasive blood pressure monitoring

3

Description

Mean Arterial Pressure

Timepoint

Before and after epidural analgesia and minutes 10, 20, 30, 40, 50, 60 after epidural analgesia and the onset and end of the second stage of labor

Method of measurement

Noninvasive blood pressure monitoring

4

Description

Heart Rate

Timepoint

Before and after epidural analgesia and minutes 10, 20, 30, 40, 50, 60 after epidural analgesia and the onset and end of the second stage of labor

Method of measurement

Noninvasive blood pressure monitoring

5

Description

satisfaction

Timepoint

After baby birth

Method of measurement

Ask the patient about the amount of satisfaction

6

Description

Total dose of lidocaine

Timepoint

After delivery and catheter exit

Method of measurement

Calculate the number of lidocaine ampoules

7

Description

Newborn Apgar

Timepoint

The first and fifth minutes after birth

Method of measurement

Examination and calculation on Apgar score

8

Description

Nausea & Vomiting

Timepoint

During the first and second stages of labor

Method of measurement

Observation and ask the patient

9

Description

Sedation

Timepoint

Before and after epidural analgesia and minutes 10, 20, 30, 40, 50, 60 after epidural analgesia and the onset and end of the second stage of labor

Method of measurement

Using Ramsay Score

10

Description

Pruritus

Timepoint

Before and after epidural analgesia and minutes 10, 20,

30, 40, 50, 60 after epidural analgesia and the onset and end of the second stage of labor

Method of measurement

VAS Of Pruritus

11

Description

Paresthesia of Lip

Timepoint

During the first and second stages of labor

Method of measurement

Ask the patient

12

Description

The amount of ephedrine consumed

Timepoint

After delivery and catheter exit

Method of measurement

Calculate the amount of ephedrine consumed in mg

13

Description

Need to do cesarean section

Timepoint

After baby birth

Method of measurement

observation

Intervention groups

1

Description

First intervention group: In bolus group patients after receiving 500 ml of Ringer's serum and in sitting position, first with 18 G epidural needle (Tohy) in L3-L4 space and using the loss of resistance technique, we determine the epidural space. Then place the epidural catheter in the epidural space and In the bolus group, 10 ml of lidocaine 1% plus 1 ml of sufentanil is injected into the epidural space at the same time, and then every one hour 10 ml of lidocaine 1% is bolusly injected into the epidural space regularly until delivery by anesthesiologist.

Category

Treatment - Drugs

2

Description

Second intervention group: After receiving 500 ml of Ringer's serum and in sitting position, the first 18G epidural needle (Tohy) is inserted into space L3-L4 and using the loss of resistance technique, we determine the epidural space. Then the epidural catheter is placed in the epidural space and in the continuous infusion group, at first, 10 ml of lidocaine 1% plus 1 ml of sufentanil bolusly is injected into the epidural space, and Lidocaine 1% is then infused continuously at a rate of 10 ml / hour with continuous infusion pump that is adjusted by anesthesiologist and infused into the epidural space until delivery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian

Street address

Fatemieh Hospital, Pasdaran Street

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 7012

Fax

+98 81 3828 3939

Email

hp.fatemieh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Mahdie Street, Hamadan University of Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

6517838678

Phone

+98 81 3838 0717

Fax

+98 81 3838 0130

Email

vc_research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Nahid Manouchehrian

Position
Associate Professor of Hamadan University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Fatemieh Hospital, Pasdaran Street

City
Hamadan

Province
Hamadan

Postal code
6517789971

Phone
+98 81 3827 7012

Fax
+98 81 3828 3939

Email
manuchehriann@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Nahid Manouchehrian

Position
Associate professor of Hamadan University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Fatemieh Hospital, Pasdaran Street

City
Hamadan

Province
Hamadan

Postal code
6517789971

Phone
+98 81 3827 7012

Fax
+98 81 3828 3939

Email
manuchehriann@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Nahid Manouchehrian

Position
Associate professor of Hamadan Medical University

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Fatemieh Hospital, Pasdaran Street

City
Hamadan

Province
Hamadan

Postal code
65177-89971

Phone
+98 81 3827 7012

Fax
+98 81 3828 3939

Email
manuchehriann@gmail.com

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