# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**

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**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

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**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

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## Sponsors / Funding sources

**1**

**Sponsor**

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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**

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Hamedan University of Medical Sciences

**Full name of responsible person**
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**Position**
Associate Professor of Hamadan University of Medical Sciences

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

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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