

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of intra techal injection of fentanyl and sufentanil on the onset, duration and quality of analgesia in vaginal delivery under spinal anesthesia .

Protocol summary

Study aim

Comparison of intra techal injection of fentanyl and sufentanil on onset, duration and quality of analgesia in vaginal delivery under spinal anesthesia .

Design

50 patients are entered into a double-blind, phase 2-3 clinical trial and randomly assigned into 4 blocks and entered into one of the two groups of spinal analgesia by Fentanyl and Sufentanil.

Settings and conduct

In patients candidate for labor analgesia in Fatemiyeh Hospital of Hamadan ,randomly 1.5 ml fentanyl or sufentanil is injected intratechally .So that, patient, evaluator and anesthesiologist do not know the type of injected drug.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with class 1 and 2 of ASA ; Second pregnancy Gestational age 36 to 40 weeks; Aged 18 to 45 years ; Cervical dilatation is more than 5 cm
Exclusion Criteria: Heart disease; Diabetes; Spinal anesthesia Contraindication ; History of opioid use in 24 hours before delivery.

Intervention groups

Patients were placed in a sitting position and 25 Quinke needle inserted into L3-L4 or L4-L5 space and after aspiration of cerebrospinal fluid , 1.5 ml of Fentanyl or Sufentanil(in group A or B) is injected into the subarachnoid space by an anesthetist who has no known medication .

Main outcome variables

After the spinal block, maternal vital signs; VAS of pain; maternal sedation score and FHR are determined every 5 minutes to 15 minutes, and then every 15 minutes to 3 hours.Time to reduce pain; duration of analgesia ; patient's satisfaction; Apgar score in the first and fifth minutes; duration of the first and second stages of labor; the need for cesarean section; itching; nausea and

vomiting are also recorded in the questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N10**

Registration date: **2018-12-12, 1397/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-12, 1397/09/21**

Update count: **0**

Registration date

2018-12-12, 1397/09/21

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of intra techal injection of fentanyl and sufentanil on the onset, duration and quality of analgesia in vaginal delivery under spinal anesthesia .

Public title
The effect of spinal opioids on labor pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with class 1 and 2 of physical status(ASA) The second pregnancy Gestational age 36 to 40 weeks Aged 18 to 45 years old Active phase of labor(Cervical dilatation is more than 5 cm)
Exclusion criteria:
 Heart disease Diabetes Spinal anesthesia
 Contraindication(High ICP, coagulation problems, shock, anemia) History of opioid use in 24 hours before delivery

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

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

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 . In this way, according to the sample size, 12 blocks 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)
Double blinded

Blinding description
All patients, after entering the operating room using Angiocath 18, received 500 ml of Ringer serum and patient's primary vital signs are measured by a non-invasive monitoring device. Then the patient is placed in a sitting position and placed under spinal anesthesia with spinal Quincke needle number 25 in L4-L5 or L3-L4 space, and after leaving the cerebrospinal fluid from the needle tip and correcting the subarachnoid space, 1.5 ml of one of the two drugs fentanyl or sufentanil that prepared by an anesthetist nurse ((Which does not know

the study)) in syringes of the same size and shape , is drawn into sterile syringe by anesthetist and is injected into the sub-arachnoid space, in each patient two groups A or B. Thus, the patient, anesthetist (assessor), and an analyzer are not aware of any prescriptive substance.

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

Hamadan University of Medical Sciences, Mahdie Street

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6517838678

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR. UMSHA .REC.1397.223

Health conditions studied

1

Description of health condition studied

Vaginal delivery under spinal 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

Time to start analgesia

Timepoint

After doing spinal analgesia

Method of measurement

Calculation of the time from the moment of spinal analgesia is just the feeling of pain relief by the patient

2

Description

Duration of analgesia

Timepoint

Since the reduction in the patient's pain until the restart of pain

Method of measurement

Calculate the time when the vas of pain decreases to less than 4 until vas of pain increases again to more than 4.

3

Description

Quality of analgesia

Timepoint

After performing spinal analgesia every 5 minutes to 15 minutes and then every 15 minutes to 3 hours

Method of measurement

Use a 10-cm ruler to determine the vas of pain by patient

Secondary outcomes

1

Description

Mother's heart rate

Timepoint

After performing spinal analgesia every 5 minutes to 15 minutes and then every 15 minutes to 3 hours

Method of measurement

Pulse oximetry device

2

Description

Duration of the first stage of labor

Timepoint

Since the onset of labor pain before the baby's birth

Method of measurement

Calculate the dilation time of cervix at 5 cm to the full dilation of cervix.

3

Description

Duration of the second stage of labor

Timepoint

After baby birth

Method of measurement

Calculation from the time of full dilation of cervix until birth time of the baby

4

Description

Sedation Score

Timepoint

After performing spinal analgesia every 5 minutes to 15 minutes and then every 15 minutes to 3 hours

Method of measurement

Ramsay Score

5

Description

Nausea and vomiting

Timepoint

During the first and second stages of Labor

Method of measurement

Observation and ask the patient

6

Description

Itching

Timepoint

During the first and second stages of Labor

Method of measurement

Observation

7

Description

Baby Apgar

Timepoint

The first and fifth minutes after birth of the baby

Method of measurement

Apgar Score

8

Description

Fetal heart rate

Timepoint

After performing spinal analgesia every 5 minutes to 15 minutes and then every 15 minutes to 3 hours

Method of measurement

Fetal heart monitoring device

9

Description

Need to do cesarean section

Timepoint

During the first and second stages of Labor

Method of measurement

Seeing the transfer to the operating room for cesarean section

10

Description

Satisfaction

Timepoint

After baby birth

Method of measurement

Ask the patient

Intervention groups

1

Description

First intervention group: After receiving 500 ml of Ringer's serum patients were placed in a sitting position

after and 25 Quinke needle inserted into L3-L4 or L4-L5 space and after observing the coming out of cerebro spinal fluid from the sub arachnoid space, in the first group(A), 1.5 ml of fentanyl is injected by an anesthetist who has no known medication in sterile syringe and injected into the subarachnoid space.

Category

Treatment - Drugs

2**Description**

Second intervention group: After receiving 500 ml of Ringer's serum patients were placed in a sitting position after and 25 Quinke needle inserted into L3-L4 or L4-L5 space and after observing the coming out of cerebrospinal fluid from the sub arachnoid space, In the second group(B), 1.5 ml of sufentanyl is injected by an anesthetist who has no known medication in sterile syringe and injected into the subarachnoid space.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemieh Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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