

# 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)

##### Phone

+98 81 1827 7012

##### Email address

manouchehrian@umsha.ac.ir

##### 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

**City**

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**Province**

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**Postal code**

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**

Nahid Manouchehrian

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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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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

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

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**Person responsible for updating data**

**Contact**

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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**

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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