

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparision of Fentanyl -Bupivacaine and Sufentanyl -Bupivacaine for Intrathecal Labour Analgesia in pregnant women.

Protocol summary

Study aim

Comparison of the effect of fentanyl-bupivacaine and sufentanil-bupivacaine on analgesia of spinal anesthesia in pregnant women referring to Ayatollah Mousavi Hospital in Zanjan

Design

The clinical trial has two groups of intervention and control group, based on pragmatic society, with parallel, one blind, randomized groups

Settings and conduct

Firstly, women referred to Ayatollah Mousavi Hospital in Zanjan who were admitted to childbirth and in the active phase of labor in the first stage of labor, with conditions included term pregnancy and no underlying disease. Based on randomized blocking method They are divided into two groups of intervention and one control group. In the first group, 50 µg fentanyl + 2.5 mg bupivacaine and in the second group 5 µg sufentanil + 2.5 mg bupivacaine is injected by number of 25 spinal needle in position of L3-L4 or L4-L5 and after the start of the first stage of delivery (4 cm dilatation in multiparous women and due to slower than delivery 6 cm dilatation in Nulipar women), and no intervention is performed in the third group or control group. Then, the course of delivery and outcomes are studied in all three groups. People are not aware of the drug compound used.

Participants/Inclusion and exclusion criteria

Entry criteria: Women of reproductive age (15 to 35)
Term pregnancy thirty-eight weeks Starting the first stage of labor Exit criteria: patient dissatisfaction
Infection in the spinal needle entry site High blood pressure Coagulation disorders History of allergy to narcotic drugs or local anesthetics Heart disease, kidney, liver disease

Intervention groups

women referring to Ayatollah Mousavi Hospital in Zanjan who are admitted to childbirth and in the active phase of labor in the first stage of delivery with conditions of the study include term pregnancy and lack of underlying

illness, based on the randomized blocking method They are divided into two groups of intervention and one control group

Main outcome variables

Duration of first stage of labor; Duration of second stage of labor; time of onset analgesia; Level of sensory and motor block; Duration of analgesia; Type of delivery; Apgar score; Maternal satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160818029414N4**

Registration date: **2018-03-21, 1397/01/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-21, 1397/01/01**

Update count: **0**

Registration date

2018-03-21, 1397/01/01

Registrant information

Name

Vahideh Rashtchi

Name of organization / entity

Zanjan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01
Expected recruitment end date
 2018-04-20, 1397/01/31
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparision of Fentanyl –Bupivacaine and Sufentanyl –Bupivacaine for Intrathecal Labour Analgesia in pregnant women.

Public title
 Comparision of the addition of Fentanyl and Sufentanil to Bupivacaine on labor analgesia

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Pregnant woman with age between 15 to 45 and with gestational age between 38 weeks and more Negative past medical history One or two gravid
Exclusion criteria:
 Patient dissatisfaction Infection in the site of spinal needle High intracranial pressure Coagulation disorders History of allergy to narcotic drugs or anesthetics Presence of underlying disease

Age
 From **15 years** old to **45 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
 Target sample size: **90**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Blocked randomization

Blinding (investigator's opinion)
 Double blinded

Blinding description
 The mothers participating in the study after obtaining the informed consent of the spinal anesthesia and explaining the possible side effects of the medication by the anesthetist and the relevant caregiver (clinicians) without mentioning the name The analgesic group has been shown to be analgesic and the practitioner is also aware of the effects of the medication group. The outcome analyst who is the statistic consultant is also not aware of the medication used.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan univercity of medical sciences

Street address

Azadi Avenue

City

Zanjan

Province

Zanjan

Postal code

4515613113

Approval date

2017-08-08, 1396/05/17

Ethics committee reference number

ZUMS.REC.1396.95

Health conditions studied

1

Description of health condition studied

labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

labor pain

Timepoint

From the time of analgesia to the end of labor or the end of anesthesia

Method of measurement

Based on the questionnaire completed by the researcher, the time is defined in terms of minutes and pain relief based on the pain ruler.

Secondary outcomes

1

Description

Baby apgar

Timepoint

One and a five minutes after childbirth

Method of measurement

The neonatal Apgar score is based on five items: heart rate, muscle tone, baby color, respiratory effort, reflexive irritability. Heart rate less than one hundredth of a

person is more than 100 points and in the absence of a score of zero. Irregular respiratory rate score is 1 and A good cry is a score of 2, and in the absence of a score of zero. Your loose muscle is zero and if you have some degrees of flexion, the score 1 and the active motions score 2. If there is no reflexive irritation, the score is zero and in the case of change The baby's face will score one and, in the case of a severe cry, score 2. The pale or blue score is zero, the pink body and The blue endings score one and the whole pink score is 2.

2

Description

Patient satisfaction with analgesia

Timepoint

Immediately after childbirth

Method of measurement

A Visual Analogue Scale (VAS) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. It is often used in epidemiologic and clinical research to measure the intensity or frequency of various

Intervention groups

1

Description

Intervention group: Intervention group: Pregnant mothers were referred to the Mousavi Hospital in the active phase of labor and their first or second term pregnancy. 50 micrograms of fentanyl and 2.5 mg of bupivacaine were injected through the number of 25 spinal needle to space of L3-L4 or L4-L5 in sitting position.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: Intervention group: Pregnant mothers were referred to the Mousavi Hospital in the active phase of labor and their first or second term pregnancy. 5 micrograms of Sufentanyl and 2.5 mg of bupivacaine were injected through the number of 25 spinal needle to space of L3-L4 or L4-L5 in sitting position.

Category

Treatment - Drugs

3

Description

Control group: Pregnant mothers who are referred to Mousavi Hospital, who are in the active phase of labor, and their first or second term pregnancy, are examined for the course of labor.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mousavi Hospital

Full name of responsible person

Zohre Pishgahi

Street address

Gavazang Avenue

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Zanjan

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Zanjan

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45139566183

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Email

drz.pishgahi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Alireza shogli

Street address

Ayatollah Musavi hospital ., Gavazang road

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Zanjan

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Phone

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Email

drz.pishgahi@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

vrashtchi@gmail.com

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

zohre pishgahi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Position

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Latest degree

Specialist

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Anesthesiology

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Person responsible for updating data

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Name of organization / entity

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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