Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparision of Fentanyl –Bupivacaine and Sufentanyl –Bupivacaine for Inthrathecal 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

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Name of organization / entity
Zanjan university of medical sciences

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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 Inthrathecal 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr.Alireza shogli
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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

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
Gynecology and Obstetrics

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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