

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intrathecal injection of fentanyl and sufentanil along with bupivacaine in the onset, duration and quality of painless labor; A randomized double-blind clinical trial

Protocol summary

Study aim

Comparison of intrathecal injection of fentanyl and sufentanil along with bupivacaine in onset, duration and quality of painless labor.

Design

A double-blind, randomized clinical trial with parallel groups design of 80 patients.

Settings and conduct

This study is conducted in Alzahra Hospital in Rasht. After explaining the purpose and method of the research, informed consent will be obtained. Pregnant mothers will be carefully placed in a sitting position. In sterile conditions, a 25-size needle will be entered into the intraspinal space through lumbar vertebrae L3-L4 or L4-L5, and the injection will be performed. Pulse oximetry, blood pressure and electrocardiography will be evaluated continuously until the end of the operation. The sensory and motor block will be continuously monitored after injection. The pain score for labor analgesia will also be evaluated based on VAS. After transferring mothers to recovery and stabilization of vital signs, the level of satisfaction with the quality of analgesia will be measured by numerical rating scale (NRS).

Participants/Inclusion and exclusion criteria

Inclusion criteria: pregnant mothers over 18 years with term pregnancy and single fetus and ASA class I or II, in the advanced stage of labor with cervical dilatation of at least 5 cm and tending to have painless labor. Inclusion criteria: obesity, endocrine disease, drug abuse, allergy to study drugs and regional anesthesia contraindications.

Intervention groups

In the bupivacaine-fentanyl group, 2.5 milligrams of bupivacaine (manufactured by Aspen Company) and 25 micrograms of fentanyl (manufactured by Darupakhsh Company, Iran) and in the bupivacaine-sufentanil group, 2.5 milligrams of bupivacaine and 2.5 micrograms of sufentanil (manufactured by Aburihan Company, Iran)

will be injected.

Main outcome variables

Labor pain score and pregnant mothers' satisfaction with the quality of analgesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230403057808N1**

Registration date: **2023-04-19, 1402/01/30**

Registration timing: **prospective**

Last update: **2023-04-19, 1402/01/30**

Update count: **0**

Registration date

2023-04-19, 1402/01/30

Registrant information

Name

Samaneh Ghazanfar Tehran

Name of organization / entity

Country

Iran (Islamic Republic of)

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tehranisamaneh88rasht@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of intrathecal injection of fentanyl and sufentanil along with bupivacaine in the onset, duration and quality of painless labor; A randomized double-blind clinical trial

Public title
Intrathecal injection of fentanyl and sufentanil along with bupivacaine in painless labor

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Primiparous or multiparous pregnant mothers with term pregnancy Single fetus American Society of Anesthesiologists' (ASA) classification I, II In the advanced stage of labor with cervical dilation at least 5 centimeter in Primiparous and at least 4 centimeter in multiparous mothers Age more than 18 years Tending to have painless labor
Exclusion criteria:
 Refusal to participate in the study by pregnant mothers Obesity Endocrine disease Drug abuse Allergy to study drugs Regional anesthesia contraindications such as coagulopathy, high intracranial pressure and infection of injection site .

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible pregnant mothers who have given informed consent to participate in the study will be assigned to one of the two groups of bupivacaine with fentanyl and bupivacaine with sufentanil by an Anesthetist technician who is not involved in the study, with a random sequence in blocks of four created by computer (WinPepi software11.65), with the sequence of randomization blocks in a ratio of 1:1.Allocation concealment will be used for implementing the random sequence of participants in the study. So before assigning the person, the assigned group will not be This will prevent participants and researchers from knowing about the subsequent allocation. In order to maintain the random sequence, the outer surface of the envelopes is

numbered in the same order. In order to maintain the random sequence, the outer surface of the envelopes will be numbered in the same order. At the time of registration of eligible patients for the study, one of the envelopes will be opened and the patient will be a candidate for one of the two methods of analgesia.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to double-blind the study, the anesthesiologist who prepares the study drug also performs the neuraxial block in order to take the necessary actions in case of side effects. Data collection will be done by the anesthesia assistant responsible for the project. In this study, the pregnant mother and the evaluator will be unaware of the type of drug used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht

City

Rasht

Province

Guilan

Postal code

4144654839

Approval date

2023-03-01, 1401/12/10

Ethics committee reference number

IR.GUMS.REC.1401.598

Health conditions studied

1

Description of health condition studied

Intrathecal injection of fentanyl and sufentanil in combination with bupivacaine in onset, duration and quality of painless labor

ICD-10 code

O75.9

ICD-10 code description

Complication of labor and delivery, unspecified

Primary outcomes

1

Description

Mean time of onset of sensory block

Timepoint

At zero, 5, 10, 15, 30, 45, 60, 90, 120 and 150 minutes after injection

Method of measurement

Pinprick response in both lower limbs

2

Description

Mean time of duration of sensory block

Timepoint

At zero, 5, 10, 15, 30, 45, 60, 90, 120 and 150 minutes after injection

Method of measurement

Pinprick response in both lower limbs

3

Description

The state of motor block

Timepoint

At zero, 5, 10, 15, 30, 45, 60, 90, 120 and 150 minutes after injection

Method of measurement

Bromage test: zero (full flexion of knees and ankles), one (ability to move only knees), two (ability to move only legs), and three (inability to move knees and feet)

4

Description

Labor pain score

Timepoint

At zero, 5, 10, 15, 30, 45, 60, 90, 120 and 150 minutes after injection

Method of measurement

Based on visual analog scale as 1-10

5

Description

Satisfaction status of pregnant mothers with the quality of analgesia

Timepoint

After transferring pregnant mothers to recovery and stabilization of vital signs

Method of measurement

Numerical Rating (NRS) based on percentage

Secondary outcomes

1

Description

Drug complications: (Blood pressure drop more than 20% of baseline, itching, chills, nausea and vomiting, cases leading to cesarean section)

Timepoint

The duration of the procedure

Method of measurement

Observance

Intervention groups

1

Description

Intervention group1: In sterile conditions, a 25-size needle (B.Brown company) will be entered into the intraspinal space through lumbar vertebrae L3-L4 or L4-L5, and after ensuring the flow of cerebrospinal fluid, the injection will be performed. In the bupivacaine-fentanyl group, 2.5 milligrams of bupivacaine (manufactured by Aspen Company) will be injected with 25 micrograms of fentanyl (manufactured by Darupakhsh Company, Iran). The total volume of the solution is one milliliter.

Category

Treatment - Surgery

2

Description

Intervention group2 : In sterile conditions, a 25-size needle (B.Brown company) will be entered into the intraspinal space through lumbar vertebrae L3-L4 or L4-L5, and after ensuring the flow of cerebrospinal fluid, the injection will be performed. In the bupivacaine-sufentanil group, 2.5 milligrams of bupivacaine (manufactured by Aspen Company) will be injected along with 2.5 micrograms of sufentanil (manufactured by Aburihan Company, Iran). The total volume of the solution is one milliliter.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Samaneh Ghazanfar Tehran

Street address

Alzahra Hospital, Shahid Siadati Avenue, Namjoo Street, Rasht

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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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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Samaneh Ghazanfar Tehran

Position

assistant professor, Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

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Latest degree

Master

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