

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Effectiveness of Epidural Anesthesia with Two Different Combination, Bupivacaine plus Meperidine versus Bupivacaine Plus Fentanyl in Duration of Labor and Cesarean Section Rate

Protocol summary

Study aim

Comparison of the Effectiveness of Epidural Anesthesia with two different combination, Bupivacaine Plus Fentanyl versus Bupivacaine plus Meperidine in Duration of Labor and Cesarean Section Rate

Design

In this study, 264 eligible women who are candidates for normal delivery and are included in the study and will be randomly divided into two groups after obtaining informed consent.

Settings and conduct

This study will be conducted on women referring to Arash Women's Hospital. Once the informed consent has been achieved, randomization will be performed. The random allocation list is only available to the group's epidemiologist and participants and researchers as well as the statistics counselor will be unaware of how the participants are assigned. For subjects after infusion of 7 cc / kg of ringer serum after confirmation of the patient entering the active phase of the first stage of labor, appropriate monitoring is performed and patient will be placed in a sitting position. After desensitizing the needle insertion place with two to three milliliters of lidocaine 2%, 18-gauge epi-dural needle will be inserted by using the loss of resistance technique. after a test dose with 3 ml of lidocain plus epinephrine, Epidural Anesthesia will be done with bupivacaine plus fentanyl in the first group and with bupivacaine plus meperidine in the second group and the catheter will be fixed in the epidural space. The patient then will be place in sleeping position and will be obsrved untill delivery .if be necessary, a vaginal examination is performed in the lithotomy position.

Participants/Inclusion and exclusion criteria

Patients participating in the study must be aged between 18 and 40 years old, tendency to painless delivery, ASA Class I, and II-BMI <35. Women with obstetrical or

medical contraindication (mitral valve stenosis) for NVD are not included in the study.

Intervention groups

In the first group, 15 cc of bupivacaine 125 % with 50 µg fentanyl and in the second group 15 cc bupivacaine 125 % with 25 mg of meperidine is injected into the epidural space and the catheter is fixed in the epidural spaces.

Main outcome variables

- Duration of the active phase of labor - Duration of the second stage of labor - Score of Pain Relief - Cesarean section Rate - Apgar Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170917036227N1**

Registration date: **2018-01-14, 1396/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-14, 1396/10/24**

Update count: **0**

Registration date

2018-01-14, 1396/10/24

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 9922

Email address

mvahid@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Epidural Anesthesia with Two Different Combination, Bupivacaine plus Meperidine versus Bupivacaine Plus Fentanyl in Duration of Labor and Cesarean Section Rate

Public title

Effect of Epidural Anesthesia on the Progression of Labor by Using Meperidine Compared to Fentanyl

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients tendency for Painless labor Age range between 18 to 40 years BMI smaller than 35 ASA Class I, II

Exclusion criteria:

Obstetrics Contraindication for normal delivery Spinal Deformity Coagulopathy Subacute illness Medical Contraindication for natural delivery like Mitral valve stenosis

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **264**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 264 people, with 132 people in each group. Block randomization method was designed by epidemiologist using stata version 13 software. The number of blocks considered is 6.

Blinding (investigator's opinion)

Double blinded

Blinding description

The random allocation list for patients is solely available to the epidemiologist. To hide the random allocation process, 264 sequences of treatments will be written accordingly, and then the cards will be placed in sealed envelopes. On each 10-digit random code packet, the order is written and the framework is written that the

patient identification number is relevant and the methodologist will simply be aware of the design of the code. When an anesthesiologist announces the eligibility of a patient, the methodologist will provide the anesthesiologist with the envelope. The analgesia method is selected based on the type mentioned in the envelope. None of the patients should be aware of the type and treatment process they are seeking. Also, the person evaluating the outcomes is the third person who is unaware of the random allocation process and type of treatment. To analyze the data, a statistician who is separate from the study process and who is unaware of all the processes performed will be used.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Qods st, Keshavarz Blvd

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Tehran

Province

Tehran

Postal code

1417653761

Approval date

2016-08-09, 1395/05/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.427

Health conditions studied**1****Description of health condition studied**

epidural anesthesia during labor and delivery

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes**1****Description**

Apgar Score

Timepoint

after intervention

Method of measurement

Scoring according to apgar score checklist

2**Description**

Duration of the active phase of labor

Timepoint

after intervention

Method of measurement

minutes and hours

3**Description**

Duration of the second stage of labor

Timepoint

after intervention

Method of measurement

minutes and hours

4**Description**

Score of Pain Relief

Timepoint

During Labor

Method of measurement

Visual Scale

5**Description**

Cesarean section Rate

Timepoint

after intervention

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups**1****Description**

In the first group, Epidural Anesthesia with 15 cc of bupivacaine 125 % with 50 µg fentanyl

Category

Treatment - Other

2**Description**

In the second group, Epidural Anesthesia with 15 cc of bupivacaine 125 % with 50 µg meperidine

Category

Treatment - Other

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

Arash Women's Hospital

Full name of responsible person

Dr Fatemeh Jafarzadeh

Street address

Eastern 162th St.,Baghdarnia st.,Resalat Highway, Tehranpars, Tehran ,Iran.

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

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Web page address<http://vcr.tums.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Fatemeh Jafarzadeh

Position

Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr Marzieh Vahid Dastjerdi

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Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

because we plan to use our data in another studies thus
we dont intresting to sharring that

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable