Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Bsing 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
City
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.
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Email
Dr.fatemeh.gafarzadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Qods St, Keshavarz Blv
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Postal code
1417653761
Phone
+98 21 8163 3619
Fax
+98 21 8163 3611
Email
rmo@tums.ac.ir
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

Street address

Arash Women's Hospital, Rashid Ave,Tehranpars, Reslat highway

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1653915981

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+98 21 7771 9922

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Email

dr.fatemeh.gafarzadeh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Marzieh Vahid Dastjerdi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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

City

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Person responsible for updating data

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

Street address

Arash women's hospital, Rashid Ave,Tehranpars, Reslat highway

City

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Postal code

1653915981

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Fax

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Email

dr.fatemeh.gafarzadeh@gmail.com

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