Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Assessment of the Effect of Epidural versus Spinal Analgesia on Labor Length and Maternal Satisfaction

Protocol summary

Study aim

Comparision of the Effect of Epidural versus Spinal Analgesia on Labor Length and Maternal Satisfaction

Design

This study was designed as a double-blind randomized clinical trial with a total sample size of 132 patients (88 people in Epidural and 44 people in Spinal group).

Settings and conduct

This study will be performed in Arash Women's Comprehensive Hospital. After the onset of active labor, the severity of cervical dilatation and the suitability of the pelvis for vaginal delivery will be evaluated by a gynecologist. The patient will be evaluated for CVS, RS, and the baseline heart rate, BP, RR, will be recorded in a pre-designed checklist. An intravenous line will be taken from the non-dominant hand. Ringer's lactate serum in the amount of 500 to 1000 ml is recommended as a preload. All the tools for managing the airways of the baby will be ready to run the block. Patients were randomly assigned to two groups A, or epidural analgesia with bupivacaine 0.125% at 16 cc and fentanyl 10 mg, and group B ,divide spinal analgesia with 0.5% bupiracaine into 2.5 mg or 0.5 cc with 10 mg fentanyl. Epidural and spinal anesthesia will be performed by an anesthesiologist. The variables will then be collected in a pre-made checklist among patients

Participants/Inclusion and exclusion criteria

All women who are aged 18 to 35 years will be included in the active phase of the first phase of labor and 4-5 cm dilatation and have no contraindication for anesthesia.

Intervention groups

Group A, or epidural analgesia with bupivacaine 0.125% 16 cc and fentanyl 10 mg Group B, spinal analgesia with bupiracaine 0.5% at 2.5 mg or 0.5 cc with 10 mg fentanyl

Main outcome variables

Labor Duration; Mother's Satisfaction

General information

Reason for update

Changes in sample size due to the lack of eligible and available participants for inclusion in the spinal anesthesia group: According to the consultation with the epidemiologist of the research group, a total of 132 people including 88 people in the epidural group and 44 people in the spinal group were considered in this study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121006011020N14**
Registration date: **2020-11-03, 1399/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-07, 1399/09/17**
Update count: **1**

Registration date

2020-11-03, 1399/08/13

Registrant information

Name
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Tehran University of Medical Sciences, Arash Hospital
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the Effect of Epidural versus Spinal Analgesia on Labor Length and Maternal Satisfaction

Public title

Epidural versus Spinal Analgesia in labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term pregnancy Cephalic position Active phase of the first stage of labor Normal prenatal care Cervical dilatation above 5-6 cm Aged between 18 to 35 years old Height above 150 cm Body mass index (BMI) between 18-25

Exclusion criteria:

Gestational disorders Abnormal spinal cord Dermal infections Coagulopathies Cephalopelvic disproportion (CPD) Preterm pregnancy Abnormal fetal heart rate (unstable NST)

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

The epidemiologist will assign the patient into two groups using the Stata software and the block randomization method. The size of the blocks will be six.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are unaware of the type of analgesia that is performed for them (Epidural or Spinal). The person responsible for collecting the relevant data and completing the form is unaware of the type of analgesia in patients. The anesthesiologists who perform the analgesia and the clinical caregivers of the participants know the type of analgesia.

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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+981653915981

Approval date

2019-05-13, 1398/02/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.077

Health conditions studied

1

Description of health condition studied

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Labor Duration

Timepoint

During Labor (From 0 to 4 stage of labor)

Method of measurement

Chronometer Watch

2

Description

Mother's Satisfaction

Timepoint

At the end of the study

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Epidural analgesia with bupivacaine 0.125% 16 cc and fentanyl 10 mg
Category
Treatment - Drugs

2

Description
Intervention group 2: Spinal analgesia with 0.5% bupiracaine 2.5 mg or 0.5 cc with 10 mg fentanyl
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person
Dr. Maryam Khoshideh
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Sponsors / Funding sources

1

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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
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
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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