Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of Epidural anesthesia beginning time on Labor progression and conversion of Vaginal delivery to Cesarean Section

Protocol summary

Study aim

Determining the effect of epidural anesthesia beginning time on labor progression Determining the effect of epidural anesthesia beginning time on Cesarean section rate

Design

In this study, 426 eligible women who have been admitted to the maternity ward at Arash Hospital will be selected. Participants will be randomly divided into two groups and a special code will be assigned to each participant.

Settings and conduct

This study is a randomized single blind parallel clinical trial that will be conducted in Arash Women's Hospital. Written consent will be obtained from eligible patients and after completing a demographic questionnaire, they will be examined by anesthesiologist. After anesthesiologist's permission, the participants will be randomly divided into two groups. Group 1: Includes 213 people, When the cervical dilatation reached 3 cm epidural anesthesia will be done with injecting 15 cc of bupivacaine 0.00125% plus fentanyl 50 micrograms into epidural space by an epidural catheter of size 17. Then the needle will be removed and the catheter remains in place and fixed by the adhesive to the patient's back. Every hour, with the onset of pain, we will inject the half volume of the solution through the catheter until the delivery. Group 2: Includes 213 people, When the cervical dilatation reached 5 cm will receive epidural anesthesia as described for first group. Epidural anesthesia in both group will be conducted by a same anesthesiologist.

Participants/Inclusion and exclusion criteria

All women aged 18-40 years old, in their first pregnancy that don't have any complication during pregnancy and don't have any medical or surgical contraindication for epidural anesthesia will be included in the trial after Giving written consent

Intervention groups

Group 1:early onset of epidural anesthesia at 3 cm cervical dilatation Group 1:early onset of epidural anesthesia at 5 cm cervical dilatation

Main outcome variables

The primary outcome: Progression of delivery in two groups according to the partograph chart (labor time to delivery) the length of the active stage of labor (dilation of 5 to 10 cm) and the length of the second stage. Secondary outcomes: Neonatal Apgar score, determined in accordance with the Apgar table Comparison of delivery type in two groups (vaginal to cesarean delivery)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140111016161N6**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **retrospective**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Reyhaneh Hosseini

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-01-20, 1395/11/01
Expected recruitment end date
2018-02-19, 1396/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Epidural anesthesia beginning time on Labor progression and conversion of Vaginal delivery to Cesarean Section

Public title
Epidural anesthesia beginning time and Labor progression and delivery type
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
First Pregnancy Tendency for Painless labor Age between 18 to 40 years Normal pregnancy without any complication Cervix dilatation above 3 cm
Exclusion criteria:
weight above 120 kg Height below 140 cm Cardiac arrhythmia Spinal Deformity Allergies to the drugs used in the trail Neuropathy Contraindication for Spinal Analgesia malignancy DVT Skin lesions
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **426**
Randomization (investigator's opinion)
Randomized
Randomization description
Our sample size is 426 people, with 213 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, 426 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 , Deputy of Research
Street address
Qods St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2016-12-17, 1395/09/27
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.1239

Health conditions studied

1

Description of health condition studied
Epidural Anesthesia During Labor
ICD-10 code
O74.6
ICD-10 code description
Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description
Labor progression

Timepoint
During Trial
Method of measurement
Parthographe chart (a chart in which the progression of labor is recorded in terms of labor time to delivery, length of the active stage of labor (5-10 cm dilatation) and the length of the second stage)

Secondary outcomes

1

Description
Apgar Score
Timepoint
After birth
Method of measurement
Scoring according to apgar score standard checklist

2

Description
Delivery type
Timepoint
after intervention
Method of measurement
File

Intervention groups

1

Description
Group 1: Epidural anesthesia in low dilatation (3 cm)
Category
Treatment - Drugs

2

Description
Group 2: Epidural anesthesia in high dilatation (5 cm)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women's Hospital
Full name of responsible person
Dr Reihane hoseini
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Eastern 162th St, Baghdarnia st, Resalat Highway, Tehranpars, Tehran ,Iran
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Sponsors / Funding sources

1

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Name of organization / entity
Tehran University of Medical Sciences
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
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 Reihane hoseini
Position
Assistant professor

Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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 have plan to use our data in another studies, we are not interested to sharing the data at this time
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available