

# 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

Iran (Islamic Republic of)

##### Phone

+98 21 7771 9922

##### Email address

r-hosseini@tums.ac.ir

##### 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**

Partographe 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

**Street address**

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

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Tehran

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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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Qods St, Keshavarz Blv, Tehran, Iran

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rmo@tums.ac.ir

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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 scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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Assistant professor

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Subspecialist

**Other areas of specialty/work**

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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 Reihane hoseini

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Assistant professor

**Latest degree**

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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