

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of frequency of cesarean section and the average of delivery phases between Epidural analgesia versus no analgesia in labor

#### Protocol summary

##### Summary

Aim of this study comparison of frequency of cesarean section and the average of delivery phases between Epidural analgesia versus no analgesia in labor. This study is clinical trials and double blind. 120 patients will divide in two groups. Women will done delivery with epidural anesthesia (4-6 milliliter Marcain 0/125 percent and single dose 5 micro gram Fentanyl and preservative dose Marcain 0/125 percent and 0/002 percent in 6-10 milliliter in hours) and women pregnant will perform delivery without analgesia. We will record incidence cesarean and mean of time of delivery phases after delivery. Inclusion criteria: pregnant woman; single fetus; pregnant women candidates vaginal delivery; pregnant women candidates epidural; nuliparous; ASA class I and II; 37 to 42 weeks Exclusion criteria: Mothers with more than one fetus; multiparty mothers; patients referring to urgency; Patients with topical anesthetics and narcotic; block placenta infection; failure in epidural anesthesia

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017102420258N63**

Registration date: **2017-11-16, 1396/08/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-11-16, 1396/08/25

##### Registrant information

###### Name

Fariba Farokhi

###### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor and Research, Arak University of Medical Sciences

##### Expected recruitment start date

2017-06-05, 1396/03/15

##### Expected recruitment end date

2019-06-05, 1398/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of frequency of cesarean section and the average of delivery phases between Epidural analgesia versus no analgesia in labor

##### Public title

Comparison of frequency of cesarean section and the average of delivery phases between Epidural analgesia versus no analgesia in labor

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: pregnant woman; single fetus; pregnant women candidates vaginal delivery; pregnant women candidates epidural; nuliparous; ASA class I and II; 37 to 42 weeks Exclusion criteria: Mothers with more than one fetus; multiparty mothers; patients referring to urgency; Patients with topical anesthetics and narcotic;

block placenta infection; failure in epidural anesthesia

#### Age

No age limit

#### Gender

Male

#### Phase

2-3

#### Groups that have been masked

No information

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee Arak University Of Medical Sciences

##### Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

##### City

Arak

##### Postal code

38149578558

#### Approval date

2017-05-22, 1396/03/01

#### Ethics committee reference number

IR.ARAKMU.REC.1396.38

## Health conditions studied

### 1

#### Description of health condition studied

Delivery

#### ICD-10 code

O80

#### ICD-10 code description

Single spontaneous delivery

## Primary outcomes

### 1

#### Description

incidence cesarean

#### Timepoint

after delivery

#### Method of measurement

mount

### 2

#### Description

Mean of time of delivery phases

#### Timepoint

after delivery

#### Method of measurement

Minute

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Women will done delivery with epidural anesthesia (4-6 milliliter Marcain 0/125 percent and single dose 5 micro gram Fentanyl and preservative dose Marcain 0/125 percent and 0/002 percent in 6-10 milliliter in hours)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Delivery is performed without analgesia.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani hospital

##### Full name of responsible person

Dr Maryam Shokrpour

##### Street address

Taleghani hospital, Emam Khomeini street

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of  
Medical Sciences

**Full name of responsible person**

Dr Anoshirvani

**Street address**

Vice chancellor for research, Payambar Azam  
Complex, Basij square, Sardasht, Arak

**City**

Arak

**Grant name**

-

**Grant code / Reference number**

-

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Arak University of Medical  
Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Maryam Shokrpour

**Position**

Faculty member, Gynechologist

**Other areas of specialty/work**

**Street address**

Taleghani hospital, Emamkhomeini street

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-

## Person responsible for scientific inquiries

**Contact**

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Dr Alireza Kamali

**Position**

Faculty member, Anesthesiologist

**Other areas of specialty/work**

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Valiasr Hospital, Valiasr square, Shahid Shirodi street

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-

## Person responsible for updating data

**Contact**

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Arak University of Medical Sciences

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Rezvan Rahimi

**Position**

Medical student

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*