

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison position of tilt of Pelvic and position of tilt of Position in intrauterine resuscitation during spinal anesthesia for cesarean section

#### Protocol summary

##### Summary

This study is a double blind clinical trial. One hundred patients admitted for non-emergency cases to Taleghani hospital in Arak. Inclusion criteria: ASA I, II, age: 20-35, BMI: nineteen to twenty-six Exclusion criteria: fetal distress, symptoms for start delivery, multiple pregnancy, hypertension, preeclampsia, intrauterine growth restriction, contraindication for spinal anesthesia, polyhydramnios, macrosomia. In first, researcher obtained demographic information and vital signs and arterial oxygen saturation from all patients. Then, researcher injected Ringer serum 10 ml per kg and 10 mg Metoclopramide and 50 mg Ranitidine, as premedication 15 minutes before surgery. Patients were allocated randomly (simple random) into two groups (pelvic tilt and tilt beds by 15 degrees). Spinal anesthesia was done in the space between the vertebrae of the L3-L4 or L4-L5 with needle 26 and 12.5 mg of Buivacaine injected in 15 seconds in the subarachnoid space. The patients were divided according to their group's position. Sensational block was investigated every 1 min after anesthesia and motor block measured by Bromage scale. Time of sensational block were recorded in T10 and highest Dermatomes block in 15 minutes. Mean arterial blood pressure, heart rate and arterial oxygen saturation were measured every 5 minutes to end of surgery. The fetal Apgar scores were recorded at first and fifth minute after delivery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015121325509N1**

Registration date: **2016-01-04, 1394/10/14**

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

Last update:

Update count: **0**

##### Registration date

2016-01-04, 1394/10/14

##### Registrant information

###### Name

Ali Khanidokht

###### Name of organization / entity

Arak University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3505

###### Email address

a.khanidokht@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Arak University of Medical Sciences and Health Services

##### Expected recruitment start date

2015-12-15, 1394/09/24

##### Expected recruitment end date

2017-12-15, 1396/09/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison position of tilt of Pelvic and position of tilt of Position in intrauterine resuscitation during spinal anesthesia for cesarean section

##### Public title

Effect of position during spinal anesthesia for cesarean section

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: ASA I, II, age 20-35, BMI nineteen to twenty-six Exclusion criteria: fetal distress, symptoms for start delivery, multiple pregnancy, hypertension, preeclampsia, intrauterine growth restriction, contraindication for spinal anesthesia, polyhydramnios, macrosomia

### **Age**

From **20 years** old to **35 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **100**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

In blindness patient and analyzer do not know information of classification of groups. Randomization done two groups by random number method.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Arak University of Medical Sciences and Health Services

##### **Street address**

Research Center, Payambar azam educational complex, Basij square, Sardasht

##### **City**

Arak

##### **Postal code**

38481-7-6941

#### **Approval date**

2015-06-29, 1394/04/08

#### **Ethics committee reference number**

IR.ARAKMU.REC.1394.70

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Intrauterine Resuscitation during Spinal Anesthesia for Caesarian Section

#### **ICD-10 code**

O82.0

#### **ICD-10 code description**

Delivery by elective caesarean section

## **Primary outcomes**

### 1

#### **Description**

arterial blood pressure

#### **Timepoint**

Every five minutes after intervention until end of surgery

#### **Method of measurement**

Barometer

### 2

#### **Description**

Heart rate

#### **Timepoint**

Every 5 minutes after intervention until end of surgery

#### **Method of measurement**

Pulse counting

### 3

#### **Description**

Arterial oxygen saturation

#### **Timepoint**

Every 5 minutes after intervention until end of surgery

#### **Method of measurement**

Pulse oximetry

### 4

#### **Description**

Apgar in neonate

#### **Timepoint**

First and fifth minute after end of surgery

#### **Method of measurement**

Apgar questionnaire

### 5

#### **Description**

Time of sensational block in T10

#### **Timepoint**

15 minutes after intervention

#### **Method of measurement**

chronometer

### 6

#### **Description**

time of Highest Dermatomes block

#### **Timepoint**

15 minutes after intervention

**Method of measurement**

chronometer

**Secondary outcomes**

empty

**Intervention groups****1****Description**

patient lying supine and a pillow placed under the right hip .it is 15 degrees of tilt of pelvic of patient.

**Category**

Treatment - Other

**2****Description**

researcher will put tilt angle of bed to 15 degrees to left

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Taleghani Hospital

**Full name of responsible person**

Dr Ali Khanidokht

**Street address**

Emam Khomeini street

**City**

Arak

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Arak University of Medical Sciences and Health Services

**Full name of responsible person**

Dr Mohammad Rafiee

**Street address**

Research Center, Payambar azam educational complex, Basij square, Sardasht

**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 and Health Services

**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 and Health Services

**Full name of responsible person**

Dr Ali Khanidokht

**Position**

Resident of Anesthesia

**Other areas of specialty/work****Street address**

Research Center, Payambar azam educational complex, Basij square, Sardasht

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences and Health Services

**Full name of responsible person**

Dr Hoshang Talebi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr Ali Khanidokht

**Position**

Resident of anesthesia

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a.khanidokht@arakmu.ac.ir

**Web page address**

## 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*