

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of transient neurologic symptoms induced by lidocaine and bupivacaine after spinal anesthesia in cesarean

#### Protocol summary

##### Summary

Objectives: Follow-up of patients undergoing uncomplicated spinal anesthesia have shown that some of them had suffered from pain in the lower extremities. This painful condition that starts immediately after surgery and has a spontaneous and complete improvement is called as transient neurologic symptoms. The aim of this study is to compare the transient neurologic symptoms of lidocaine and bupivacaine after spinal anesthesia in caesarean section. Design: Simple randomization, double blind, without placebo, trial phase 2, including 150 patients under elective cesarean section. Setting and conduct: spinal anesthesia will perform with the 25-G Quincke needle. Participants including major eligibility criteria: All women who are supposed to undergo elective cesarean section. Intervention: Lidocaine 5%, 75 milligrams, intrathecal injection. Bupivacaine 0.5%, 12 milligrams, intrathecal injection. Main outcome measures: Tingling and numbness in the thighs and hip, Pain in the lower back and buttocks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201404262080N15**

Registration date: **2014-05-18, 1393/02/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-05-18, 1393/02/28

##### Registrant information

###### Name

Afsaneh Norouzi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1313 7474

##### Email address

norouzi.a@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences, Vice Chancellor for Research

##### Expected recruitment start date

2014-05-22, 1393/03/01

##### Expected recruitment end date

2014-08-23, 1393/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of transient neurologic symptoms induced by lidocaine and bupivacaine after spinal anesthesia in cesarean

##### Public title

Comparison of transient neurologic symptoms after spinal anesthesia for cesarean

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. Women between 20 to 45 years old  
2. Term pregnancy  
3. Elective cesarean  
4. No history of back pain, weakness and numbness in the extremities  
Exclusion criteria: 1. Underlying diseases such as pre-eclampsia and eclampsia  
2. Hypertension  
3. Adding

epinephrine or opiate to drugs 3. Using a needle with a larger size

### Age

From **20 years** old to **45 years** old

### Gender

Female

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **150**

### 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 of Arak University of Medical Sciences

##### Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

##### City

Arak

##### Postal code

##### Approval date

2012-08-10, 1391/05/20

##### Ethics committee reference number

91-142-5

## Health conditions studied

### 1

#### Description of health condition studied

Tingling

#### ICD-10 code

R20.2

#### ICD-10 code description

Tingling sensation

## Primary outcomes

### 1

#### Description

Tingling

#### Timepoint

Immediately, 6, 12, and 24 hours after cesarean

#### Method of measurement

based on a scale of four

### 2

#### Description

Pain

#### Timepoint

Immediately, 6, 12, and 24 hours after cesarean

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

75 miligrams of 5% lidocaine, made in Gostaresh Bazargani Daroopakhsh will be injected intrathecally.

#### Category

Prevention

### 2

#### Description

12 miligrams of 0.5% bupivacaine, made in Iran Esalat company will be injected intrathecally.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani hospital

##### Full name of responsible person

Afsaneh Norouzi

##### Street address

Taleghani hospital, Imam Khomeini street, Arak, Iran

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences, Vice Chancellor for Research

**Full name of responsible person**

Dr Saeed Changizi Ashtiani

**Street address**Arak University of Medical Sciences. Basij Square.  
Sardasht. Arak. Iran**City**

Arak

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**Arak University of Medical Sciences, Vice Chancellor for  
Research**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**

Afsaneh Norouzi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**Arak University of Medical Sciences. Basij Square.  
Sardasht. Arak. Iran**City**

Arak

**Postal code****Phone**

+98 86 3313 7474

**Fax****Email**

dr.elena.rahbari@gmail.com

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

Arak University of Medical Sciences

**Full name of responsible person**

Afsaneh Norouzi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**Arak University of Medical Sciences. Basij Square.  
Sardasht. Arak. Iran**City**

Arak

**Postal code****Phone**

+98 86 3313 7474

**Fax****Email**

dr.elena.rahbari@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Afsaneh Norouzi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**Arak University of Medical Sciences. Basij Square.  
Sardasht. Arak. Iran**City**

Arak

**Postal code****Phone**

+98 86 3313 7474

**Fax****Email**

dr.elena.rahbari@gmail.com

**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*