

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of Baricity of Bupivacaine on Frequency of Transient Neurologic Syndrome (TNS) after Spinal Anesthesia for Cesarean Section

#### Protocol summary

##### Summary

In current prospective randomized double-blinded clinical trial, 230 pregnant women candidate for cesarean section, with grade I or II of American society of anesthesiology (ASA), will be enrolled. Patients with contraindications for epidural analgesia, diabetes and mental disorders excluded. Standard monitoring including non-invasive blood pressure, heart rate, pulse oximetry and electrocardiogram performed in all patients. Epidural analgesia provided using 25G Quincke needle in sitting position, between L3-L4 or L4-L5 intervertebral space. Subsequent to online randomization, patients randomly underwent 10 mg bupivacaine injection combined with 20 mg fentanyl. Study group (115) received isobaric 0.5% bupivacaine and control group (115) received hyperbaric bupivacaine. Vital signs measured regularly, during operation. Patients' demographic data, history of epidural analgesia, operation duration and analgesia duration (length of intrathecal injection till recurrence of the sensory blockage under T12 dermatome), amount of intravenous infusion, postoperative complication and subsequent treatments recorded. During 6 to 48 hours postoperative, patients evaluated in terms of transient neurologic syndrome (TNS) symptoms, symptoms onset and duration of symptoms after analgesia recovery, pain severity according to visual analogue scale (VAS) for pain (0 for painless and 10 for intolerable pain), treatment type and dosage of analgesics used to treat symptoms and final outcomes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201612237013N16**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **na**

Last update:

Update count: **0**

##### Registration date

2016-12-23, 1395/10/03

##### Registrant information

###### Name

Simin Atashkhoei

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3333 3806

###### Email address

atashkhoei@tbzmed.ac.ir

##### Recruitment status

**Not enough for processing**

##### Funding source

Vice chancellor for research of Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-12-30, 1395/10/10

##### Expected recruitment end date

2016-09-30, 1395/07/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Baricity of Bupivacaine on Frequency of Transient Neurologic Syndrome (TNS) after Spinal Anesthesia for Cesarean Section

##### Public title

Bupivacaine effect on transient neurologic syndrome after cesarean section

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: pregnant women candidate for cesarean section under epidural analgesia; Class I or II according to ASA classification. Exclusion criteria: contraindications for epidural analgesia; sensitivity to local analgesics; history of neurovascular or neuromuscular diseases; history of diabetes; history of mental disorders; intervertebral disc hernia or spinal stenosis; lower extremity neuropathy.

## Age

From **18 years** old to **40 years** old

## Gender

Male

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **230**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomly permuted blocks method used for patients randomized assignment to study groups

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Vice chancellor for research, Tabriz university of medical sciences, Daneshgah square

##### City

Tabriz

##### Postal code

#### Approval date

2016-12-05, 1395/09/15

#### Ethics committee reference number

IR.TBZMED.REC.1395.950

## Health conditions studied

### 1

#### Description of health condition studied

Epidural analgesia quality

#### ICD-10 code

O74.6

#### ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

## Primary outcomes

### 1

#### Description

time of TNS symptoms onset

#### Timepoint

6 to 48 hours after operation

#### Method of measurement

physical examination

### 2

#### Description

duration of TNS symptoms after analgesia recovery

#### Timepoint

6 to 48 hours after operation

#### Method of measurement

physical examination

### 3

#### Description

pain severity due to TNS

#### Timepoint

6 to 48 hours after operation

#### Method of measurement

visual analogue scale

## Secondary outcomes

### 1

#### Description

type of treatment used to treat TNS

#### Timepoint

6 to 48 hours after operation

#### Method of measurement

clinical document

### 2

#### Description

dosage of treatment used for TNS recovery

#### Timepoint

6 to 48 hours after operation

#### Method of measurement

clinical document

## Intervention groups

1

**Description**

Study group: will receive 10 mg 0.5% isobaric bupivacaine combined with 20 µg fentanyl, in total volume of 2.2 ml.

**Category**

Treatment - Drugs

2

**Description**

Control group: will receive 10 mg hyperbaric bupivacaine combined 20 µg fentanyl, in total volume of 2.2 ml.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Al Zahra Women's Hospital

**Full name of responsible person**

Dr. Simin Atashkhoyi

**Street address**

Baghshomal crossroad, North artesh street, Tabriz

**City**

Tabriz

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tabriz Medical University

**Full name of responsible person**

Alireza Ostadrahimi

**Street address**

Vice chancellor for research, Tabriz University of medical sciences, Daneshgah square

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz Medical University

**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**

Tabriz Medical University

**Full name of responsible person**

Dr. Simin Atashkhoyi

**Position**

Associate Professor, Specialist in Anesthesiology

**Other areas of specialty/work**

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**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*