

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

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Name of organization / entity

Tabriz University of Medical Sciences

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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

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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

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)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty