Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Siences
Country
Iran (Islamic Republic of)
Phone
+98 41 3333 3806
Email address
atashkhoii@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 sceinces, 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 sceinces, 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
Street address
Al Zahra hospital, Baghshomal square
City
Tabriz
Postal code
Phone
+98 41 3553 9161
Fax
Email
atashkhoii@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Simin Atashkhoyi
Position
Associate Professor, Specialist in anesthesiology
Other areas of specialty/work
Street address
Al Zahra hospital, Baghshomal square
City
Tabriz
Postal code
Phone
+98 41 3553 9161
Fax
Email
atashkhoii@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Simin Atashkhoyi
Position
Associate Professor, Specialist in Anesthesiology
Other areas of specialty/work
Street address
Al Zahra hospital, Baghshomal square
City
Tabriz
Postal code

Phone
+98 41 3553 9161
Fax
Email
atashkhoii@tbzmed.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