

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Incidence of transient neurologic symptom (TNS) following intrathecal anesthesia with lidocaine in cesarean and factors affecting it.

Protocol summary

Summary

Lidocaine as a local anesthetic drug is used for spinal anesthesia for many years without any concern. But recently some reports indicate this drug as a possible cause of some neurologic complications. One of these complications is transient neurologic symptom which in this study we investigated that. The incidence of this complication is very different in articles. In this study we investigated the true incidence of transient neurologic symptom with lidocaine in cesarean section and factors affecting it such as needle type. Materials and methods: sixty women candidate for cesarean delivery were randomly allocated to receive spinal anesthesia with 25-gauge Whitacre needle or Quincke needle. Spinal anesthesia will administer all of patients in sitting position using 75mg lidocaine 5%.the occurrence of TNS recorded in ten consecutive days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404211616N4**

Registration date: **2014-05-15, 1393/02/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-15, 1393/02/25

Registrant information

Name

Parisa Golfam

Name of organization / entity

Kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2014-06-01, 1393/03/11

Expected recruitment end date

2014-08-01, 1393/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Incidence of transient neurologic symptom (TNS) following intrathecal anesthesia with lidocaine in cesarean and factors affecting it.

Public title

Incidence of transient neurologic symptom following intrathecal anesthesia with lidocaine in cesarean and factors affecting it.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: women aged 20-40 years old who candidate for elective or urgent cesarean section surgery. Exclusion criteria: patients with history of chronic pain; use of analgesic drugs; neurologic diseases; morbid obese patients and diabetic patients.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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

kermanshah university of medical science

Street address

imam reza hospital,kermanshah

City

kermanshah

Postal code

Approval date

2012-03-03, 1390/12/13

Ethics committee reference number

11152/پ/707/7/آ

Health conditions studied

1

Description of health condition studied

Transient neurologic syndrom

ICD-10 code

G45.8

ICD-10 code description

Other transient cerebral ischaemic attacks and related syndromes

Primary outcomes

1

Description

Paresthesia

Timepoint

Daily during 1 weak

Method of measurement

according to patient report

2

Description

Pain

Timepoint

Daily during 1 weak

Method of measurement

According to patient report

Secondary outcomes

1

Description

Pain intensity, duration

Timepoint

After spinal anesthesia replenish

Method of measurement

History taking

Intervention groups

1

Description

25 g sprotte needle. Bupivacaine 25 g quincke needle.

Bupivacaine

Category

Treatment - Devices

2

Description

25 G sporotte needle, Lidocaine 25 G quincke needle,

Lidocaine

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Parisa Golfam

Street address

Imam reza hospital, Kermanshah

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences, Research
Department

Full name of responsible person

Farid Najafi

Street address
Kermanshah

City
Kermanshah

Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah University of Medical Sciences, Research Department

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

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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