Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Name of organization / entity

Kermanshah University of Medical Sciences

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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 neuorologic 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
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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

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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