Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of transient neurologic symptoms induced by lidocaine and bupivacaine after spinal anesthesia in cesarean

Protocol summary

Summary

Objectives: Follow-up of patients undergoing uncomplicated spinal anesthesia have shown that some of them had suffered from pain in the lower extremities. This painful condition that starts immediately after surgery and has a spontaneous and complete improvement is called as transient neurologic symptoms. The aim of this study is to compare the transient neurologic symptoms of lidocaine and bupivacaine after spinal anesthesia in caesarean section. Design: Simple randomization, double blind, without placebo, trial phase 2, including 150 patients under elective cesarean section. Setting and conduct: spinal anesthesia will perform with the 25-G Quincke needle. Participants including major eligibility criteria: All women who are supposed to undergo elective cesarean section. Intervention: Lidocaine 5%, 75 milligrams, intrathecal injection. Bupivacaine0.5%, 12 milligrams, intrathecal injection. Main outcome measures: Tingling and numbness in the thighs and hip, Pain in the lower back and buttocks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404262080N15**
Registration date: **2014-05-18, 1393/02/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

Name

Afsaneh Norouzi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of transient neurologic symptoms induced by lidocaine and bupivacaine after spinal anesthesia in cesarean

Public title

Comparison of transient neurologic symptoms after spinal anesthesia for cesarean

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Women between 20 to 45 years old 2. Term pregnancy 3. Elective cesarean 4. No history of back pain, weakness and numbness in the extremities Exclusion criteria: 1. Underlying diseases such as pre-eclampsia and eclampsia Hypertension 2. Adding

epinephrine or opiate to drugs 3. Using a needle with a larger size

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **150**

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
Ethics committee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City
Arak

Postal code

Approval date
2012-08-10, 1391/05/20

Ethics committee reference number
91-142-5

Health conditions studied

1

Description of health condition studied
Tingling

ICD-10 code
R20.2

ICD-10 code description
Tingling sensation

Primary outcomes

1

Description
Tingling

Timepoint
Immediately, 6, 12, and 24 hours after cesarean

Method of measurement
based on a scale of four

2

Description
Pain

Timepoint
Immediately, 6, 12, and 24 hours after cesarean

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
75 miligrams of 5% lidocaine, made in Gostaresh Bazargani Daroopakhsh will be injected intrathecally.

Category
Prevention

2

Description
12 miligrams of 0.5% bupivacaine, made in Iran Esalat company will be injected intrathecally.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Afsaneh Norouzi

Street address
Taleghani hospital, Imam Khomeini street, Arak, Iran

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person
Dr Saeed Changizi Ashtiani
Street address
Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran
City
Arak

Grant name

Grant code / Reference number

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

Title of funding source
Arak University of Medical Sciences, Vice Chancellor for Research

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
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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