Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of adding dexamethasone to bupivacaine on the duration of spinal anesthesia in patients with lower limb surgery

Protocol summary

Summary

The purpose of this study was to investigate the effect of adding dexamethasone to bupivacaine on duration of spinal anesthesia in patients with lower limb surgery. This study is a double blind clinical trial on 50 patients undergoing lower extremity surgery. Patients divided into two groups. Spinal anesthesia induced with spinal needle number 25 at the L4-L5 space in a sitting position. Patients in group bupivacaine received 2 mL bupivacaine 0.5% by adding 1 mL of saline mixture and patients of group bupivacaine + dexamethasone received 2 mL bupivacaine plus 4 mg of dexamethasone .Sensory level of spinal anesthesia was recorded after every 30 seconds to 20 minutes. Then sensory level measured every 5 minutes until reduced to 4. (Onset) time was recorded.(onset: the time interval between spinal anesthesia to achieve the highest level of sensory anesthesia). VAS scores according to scoring system was measured and recorded. Patients at the time of discharge, before and one month after the hospital discharge were followed up. Information on height, weight, age and sex of the patients and complications include nausea and vomiting were also recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312182963N17**
Registration date: **2014-02-02, 1392/11/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-02-02, 1392/11/13

Registrant information

Name
Shekoufeh Behdad
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Shahid Sadoughi Medical University of Yazd

Expected recruitment start date

2012-05-01, 1391/02/12

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding dexamethasone to bupivacaine on the duration of spinal anesthesia in patients with lower limb surgery

Public title

The effect of adding dexamethasone to bupivacaine on the duration of spinal anesthesia in patients with lower limb surgery

Purpose

Treatment

Inclusion/Exclusion criteria

including Criteria: 50 patients aged 18 to 70 years with ASA1,2 undergoing for lower limb orthopedic surgery.
excluding Criteria: history of cardiovascular disease;

diabetes; history of chronic pain; addiction; allergy to local anesthetics; long-term use of corticosteroids and sedatives; infection at the site of spinal anesthesia; history of neurological and psychological disorders; history of spinal surgery; history of chronic low back pain.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
shahid sadoughi medical university of yazd

Street address
bahonar square

City
yazd

Postal code
89177

Approval date
2012-05-28, 1391/03/08

Ethics committee reference number
32250/1/17/پ

Health conditions studied

1

Description of health condition studied
lower limb orthopedic surgery

ICD-10 code
T12

ICD-10 code description
Fracture of lower limb, level unspecified

Primary outcomes

1

Description
duration of spinal anesthesia

Timepoint
each 30 seconds to 20 minutes after spinal anesthesia

Method of measurement
by physical exam

Secondary outcomes

1

Description
pain in surgical site

Timepoint
after pain or reduction in sensory block in 4 dermatom

Method of measurement
VAS score by a questionare

Intervention groups

1

Description
control group: bupivacaine 2 ml + saline 1 ml

Category
Treatment - Drugs

2

Description
Intervention group: bupivacaine 2 ml+ Dexametasone 4 mg

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
yazd shahid sadoughi hospital

Full name of responsible person
habibollah hosseini

Street address
yazd shahid sadoughi hospital

City
yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for research -Shahid Sadoughi University of Medical Science

Full name of responsible person
dr hassan mozaffari
Street address
Bahonar square, Shahid Sadoughi University of Medical Science
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for research -Shahid Sadoughi University of Medical Science
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