

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 1386

Email address

drbehdad@ssu.ac.ir

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 questionnaire

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**

Shahid Sadoughi Medical Science University of Yazd

Full name of responsible person

shekoufeh behdad

Position

Associate professor

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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