

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effect of Suffentanil- dexmedetomidine in Spinal Anesthesia of Patients Undergoing lower abdominal and lower extremity surgery; a clinical trial study

Protocol summary

Summary

Objective: an increased analgesic duration, a decreased need for postoperative analgesics. Design: Sixty patients who will candidate for elective lower abdominal surgery under spinal anesthesia were entered. The randomization is done by using closed envelopes. Since this study can be effective in reducing side effects, this study is phase3. Setting and conduct: This study is a prospective clinical trial, double blind and randomized control group (placebo) that will be performed in the Hospitals of Mashhad University of Medical Sciences onto patients who are candidates for lower abdominal and lower extremity surgery under spinal anesthesia with grade 1 and 2 ASA. The randomization is done by using closed envelopes. Inclusion criteria: patients who are in the age range of 18-60 year; patient's consent of spinal anesthesia. Exclusion criteria: Addiction; history of Diabetes; history of neuropathy; history of neuromascular disease; drug allergy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082833680N3**
Registration date: **2017-09-25, 1396/07/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-25, 1396/07/03

Registrant information

Name

Farideh Golhasani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2631

Email address

golhasanif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of Suffentanil- dexmedetomidine in Spinal Anesthesia of Patients Undergoing lower abdominal and lower extremity surgery; a clinical trial study

Public title

The effect of Suffentanil- dexmedetomidine in Spinal Anesthesia of Patients Undergoing lower abdominal and lower extremity surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients who are in the age range of 18-60 year; patient's consent of spinal anesthesia.
Exclusion criteria: Addiction; history of diabetics; history

of neuropathy; history of neuromuscular disease; drug allergy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad University of Medical Sciences; International
Offic Administration Center(Qoreishi Building) ;
Daneshgah St., Mashhad

City

Mashhad

Postal code

13944-91388

Approval date

2016-02-03, 1394/11/14

Ethics committee reference number

IR.MUMS.fm.REC.1394.547

Health conditions studied

1

Description of health condition studied

Lower abdominal and lower extremity surgery under
spinal anesthesia

ICD-10 code

F44.6

ICD-10 code description

Dissociative anaesthesia and sensory loss

Primary outcomes

1

Description

Duration of sensory and motor blockade

Timepoint

After surgery

Method of measurement

Time

2

Description

Return of hemodynamic changes blocked

Timepoint

After surgery

Method of measurement

Questionnare

3

Description

Housing consumption

Timepoint

After surgery

Method of measurement

Dosage

Secondary outcomes

1

Description

Age

Timepoint

Before intervention

Method of measurement

Years

2

Description

Sex

Timepoint

Before intervention

Method of measurement

Male of female

Intervention groups

1

Description

The control group received 15 mg bupivacaine plus 3 µg
of sufentanil

Category

Placebo

2

Description

The intervention group received 15 mg bupivacaine plus 3 µg of sufentanil and 10 µg doxedemodoimidine to spinal anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Mojtaba Karimi

Street address

Department of Anesthesiology, Imam Reza Hospital, Square Taghiabad, Khorasan Razavi

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mahyar Mirheidari

Street address

Mashhad University of Medical Sciences; International Offic Administration Center (Qoreishi Building) ; Daneshgah St., Mashhad.

City

Mashhad

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, Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mojtaba Karimi

Position

Resident/ Colleague

Other areas of specialty/work

Street address

Department of Anesthesiology, Imam Reza (AS) Hospital, Square Taghi-Abad

City

Mashhad

Postal code

9137913316

Phone

+98 518022711

Fax

Email

Kaimim931@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mojtaba Karimi

Position

Resident of anesthesia

Other areas of specialty/work

Street address

Department of Anesthesiology, Imam Reza (AS) Hospital, Square Taghi-Abad Khorasan Razavi

City

Mashhad

Postal code

Iran

Phone

+98 518022711

Fax

Email

Kaimim931@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farideh Golhasani

Position

Master

Other areas of specialty/work

Street address

Square of Taghi Abad, Imam Reza Hosital, Anesthesia Research Center. Mashhad

City

Mashhad

Postal code

9137913316

Phone

+98 38538659

Fax

Email

golhasanif1@mums.ac.ir

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