

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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

Questionnaire

### 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 Office 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*