

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### A Comparison of hemodynamic changes between Dexmedetomidine infusion and Remifentanyl infusion for controlled hypotensive anesthesia in lumbar discopathy surgery

#### Protocol summary

##### Summary

The aim of this study was to compare the hemodynamic changes in patients undergoing lumbar discopathy surgery between two continuous infusions of Dexmedetomidine and remifentanyl during anesthesia with controlled low blood pressure, which was designed as a randomized, triple-blind clinical trial. In this study, the patient, clinician and the person responsible for the statistical analysis will be blind regarding the study groups. Inclusion criteria are patients undergoing lumbar discopathy surgery in physical conditions I and II, and exclusion criteria including any kind of bleeding or coagulation disorders, history of uncontrolled or severe hypertension, use of anticoagulant drugs, history of lumbar discopathy surgery and history of trauma to the lumbar spine. A total of 60 patients aged 20-65 years will be randomly assigned to control and intervention groups. computerized random numbers will be used for randomization. The study method is that for the general anesthesia, the same drug regimen will be used for both groups, and in the intervention group, the dose of Dexmedetomidine is 0.7-0.3 micrograms per kilogram body weight per hour plus propofol of 150-50 micrograms per kilogram of body weight per minute will be continuously injected. In the control group, 1-0.1 µg of Remifentanyl per kg body weight per minute plus the same amount of propofol is injected with the same quality. The primary variables of this study are changes in the patient's blood pressure, the amount of patient's bleeding during surgery, and the amount of urinary output. Secondary variables are the time interval between extubation and complete consciousness, the duration of the surgery, and the time that there is a need to administer analgesic drugs after surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017083136009N1**

Registration date: **2017-11-07, 1396/08/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-07, 1396/08/16

##### Registrant information

##### Name

Seyed Alireza Monajjem Zadeh

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3336 7543

##### Email address

salirezam82@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2017-10-23, 1396/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
A Comparison of hemodynamic changes between Dexmedetomidine infusion and Remifentanyl infusion for controlled hypotensive anesthesia in lumbar discopathy surgery

**Public title**  
A comparison between changes in cardio-vascular variables with the method of continuous infusion of Dexmedetomidine and Remifentanyl for controlled hypotensive anesthesia in lumbar discopathy surgery

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
Inclusion criteria: patients with lumbar discopathy of physical state I and II. Exclusion criteria: any blood disorders and coagulative disorders; history of uncontrolled high blood pressure; taking anti-coagulative drugs; history of lumbar discopathy surgery; history of lumbar trauma

**Age**  
From **20 years** old to **65 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Triple 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 Ahvaz Jundishapur University of Medical Sciences

##### Street address

Research Deputy, Ahvaz Jundishapur University of Medical Sciences, Daneshgah Square, Ahvaz

##### City

Ahvaz

##### Postal code

#### Approval date

2017-06-17, 1396/03/27

#### Ethics committee reference number

IR.AJUMS.REC.1396.311

## Health conditions studied

### 1

#### Description of health condition studied

Lumbar discopathy

#### ICD-10 code

M51

#### ICD-10 code description

Other intervertebral disc disorders

## Primary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Before the surgery, during the surgery, after the surgery

#### Method of measurement

Invasive arterial blood pressure monitoring

### 2

#### Description

bleeding

#### Timepoint

Before the surgery, during the surgery, after the surgery

#### Method of measurement

Calculation the amount of bleeding: the blood in the bottle of the suction machine in addition to the blood in the gases

### 3

#### Description

Urinary output

#### Timepoint

Before the surgery, during the surgery, after the surgery

#### Method of measurement

The volume of urine accumulated in the urine bag

## Secondary outcomes

### 1

#### Description

The interval between extubation and complete consciousness

#### Timepoint

After the surgery

#### Method of measurement

observation

### 2

#### Description

duration of the surgery  
**Timepoint**  
After the surgery  
**Method of measurement**  
observation

### 3

**Description**  
The time that there is a need to prescribe an analgesic  
**Timepoint**  
After the surgery  
**Method of measurement**  
observation

## Intervention groups

### 1

**Description**  
Intervention group: continuous infusion of  
Dexmedetomidine , 0.7-0.3 µg per kg body weight per  
hour plus continuous infusion of propofol, 150-50 µg per  
kg body weight per minute  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: Continuous infusion of Remifentanyl, 1-0.1  
micro-grams per kg body weight per hour plus  
continuous infusion of propofol, 150-50 micro-grams per  
kilogram body weight per minute  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Golestan Hospital  
**Full name of responsible person**  
Mahdis Vakili  
**Street address**  
Golestan Hospital, Golestan alley, Ahvaz  
**City**  
Ahvaz

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Ahvaz Jundishapur University of Medical Sciences  
**Full name of responsible person**  
Dr. SHrif Makhmal Zadeh  
**Street address**  
Ahvaz Jundishapur University of Medical Sciences,

Daneshgah Square, Ahvaz  
**City**  
Ahvaz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ahvaz Jundishapur 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**  
Ahvaz Jundishapur University of Medical Sciences  
**Full name of responsible person**  
Mahdis Vakili  
**Position**  
Consultant  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Consultant

**Other areas of specialty/work**

**Street address**

Ahvaz Jundishapur University of Medical Sciences,  
Daneshgah Square, Ahvaz

**City**

Ahvaz

**Postal code**

**Phone**

## 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*