

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### Comparison the effect of combination of Propofol-Remifentanil-Dexmedetomidine on hemodynamic parameters and postoperative complications in spine and spinal cord surgery.

#### Protocol summary

##### Summary

This study investigated the hemodynamic stability more effectively and better and reduce side effects after surgery and anesthesia (nausea, vomiting, shivering and pain) by comparing the type of drug used Remifentanyl-Propofol combination means that as common standard methods known and used and Dexmedetomidine by adding to the mix and comparing its effects with each other . Inclusion criteria: patients undergoing spine and spinal-class American Society of Anesthesiologists class (I-II) and exclusion criteria: patients with a history of severe systemic disease; body mass index greater than 30; hypertension (Blood Pressure greater than 140/90); severe respiratory diseases; symptomatic uncontrolled heart disease; diabetic patients. In this study 60 patients divided In two groups of 30 cases of 20 to 60 years. In the first group (D) 15 minutes before induction, infusion of Dexmedetomidine and Remifentanil started and in group (R) 15 minutes before induction, infusion of Remifentanil alone begun and then induction of general anesthesia in both groups with Propofol and neuromuscular relaxant (Cis-atracurium) performed and and patients are intubated. Blood pressure and Heart rate will be collected 15 minutes before incubation ,intubation time, two minutes after intubation, time change positions, change positions and two minutes after 15,30,45,90, and the repositioning during surgery minute, two minutes after switching positions. and before two minutes and thirty minutes and washed minutes after intubation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016101630327N1**  
Registration date: **2016-11-30, 1395/09/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-11-30, 1395/09/10

##### Registrant information

###### Name

Rasoul Mahdavi Jafari

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3427 6338

###### Email address

rasoul.mahdavijafari@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2016-12-20, 1395/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of combination of Propofol-Remifentanil-Dexmedetomidine on hemodynamic parameters and postoperative complications in spine and

spinal cord surgery.

**Public title**  
The effect of an anesthetic combination drug containing Propofol-Remifentanil-Daxmedetomidine on blood pressure and heart rate and postoperative complications in spine and spinal cord surgery.

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
Inclusion criteria: patients undergoing spine surgery and spinal referring to Imam Reza Kermanshah American Society of Anesthesiologists class (I-II). Exclusion criteria: patients with a history of severe systemic disease; body mass index greater than 30; patients with a history of high blood pressure (Blood Pressure greater than 140/90); severe respiratory diseases does not control; symptomatic heart disease; diabetic patients; consumers beta-blocker drugs; drug-addicted patients; patients with more than one laryngoscopy; the extreme sensitivity to drugs personality disorder; patients with more than 750 cc of blood during surgery.

**Age**  
From **20 years** old to **60 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)**  
Double blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kermanshah University of Medical Sciences Ethics Committee

##### Street address

Beheshti Blvd., Kermanshah University of Medical Sciences headquarters

##### City

Kermanshah

##### Postal code

6715847141

#### Approval date

2016-06-08, 1395/03/19

#### Ethics committee reference number

KUMS.REC.1395.173

## Health conditions studied

### 1

#### Description of health condition studied

effect of drug

#### ICD-10 code

T88.7

#### ICD-10 code description

Unspecified adverse effect of drug or medicament

## Primary outcomes

### 1

#### Description

Blood Pressure

#### Timepoint

15 minutes before induction, intubation time, two minutes after intubation, time of change position, and two minutes after the change of position, intraoperative period in minutes of 15,30,45,90, time of repositioning, two minutes after switching position. and before extubation, two, thirty and sixty minutes after extubation.

#### Method of measurement

in mmHg using mercuric manometer

### 2

#### Description

Heart Rate

#### Timepoint

15 minutes before induction, intubation time, two minutes after intubation, time of change position, and two minutes after the change of position, intraoperative period in minutes of 15,30,45,90, time of repositioning, two minutes after switching position. and before extubation, two, thirty and sixty minutes after extubation.

#### Method of measurement

number of heart rate in one minute

## Secondary outcomes

### 1

#### Description

Shivering

#### Timepoint

Postoperative

#### Method of measurement

Standard questionnaire

## 2

### Description

Nausea

### Timepoint

Postoperative

### Method of measurement

VAS

## 3

### Description

Vomiting

### Timepoint

Postoperative

### Method of measurement

VAS

## Intervention groups

### 1

#### Description

15 minutes before time of induction, Daxmedetomidine 0.6mic / kg / h and remifentanil 1mic/Kg/min are infused, at the time of induction Propofol 1-2.5 mg/Kg and neuromuscular blocking drug (Cisatracurium) 0.15 mg/Kg are injected and patient are intubated.

#### Category

Prevention

### 2

#### Description

15 minutes before time of induction, Remifentanil 1mic/Kg/min is infused, at the time of induction Propofol 1-2.5 mg/Kg and neuromuscular blocking drug (Cisatracurium) 0.15 mg/Kg are injected and patient are intubated.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Mohammad Javad Moradi

##### Street address

Sorkhe Lijhe Street

##### City

Kermanshah

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Farid Najafi

#### Street address

Beheshti Blvd, Kermanshah University of Medical Sciences headquarters

#### City

Kermanshah

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Mohammad Javad Moradi

##### Position

Resident of Anesthesiology

##### Other areas of specialty/work

##### Street address

Beheshti Blvd., Kermanshah University of Medical Sciences headquarters

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Khosro Farhadi

##### Position

Assistant 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*

**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohammad Javad Moradi

**Position**

Resident of Anesthesiology

**Other areas of specialty/work****Street address**

Beheshti Blvd., Kermanshah University of Medical Sciences headquarters