Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 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 Remientanyl-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 afte rintubation, 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

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Kermanshah University of Medical Sciences
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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 afte 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 afte 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
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Person responsible for scientific inquiries

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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