Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Dexmedetomidine and Remifentanil in the Anesthesia for Direct Laryngoscopy: A Randomized Clinical Trial

Protocol summary

Study aim

We aim to compare the effect of dexmedetomidine with remifentanil on hemodynamics parameters, , propofol consumption and postoperative respiratory depression, sedation score, postoperative pain and nausea& vomiting during direct laryngoscopy.

Design

In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 60 patients who candidate for direct laryngoscopy will be enrolled in the study. Eligible patients will be randomly allocated into two equal A, and B groups by simple randomization .

Settings and conduct

This study will be done in operating room.All of the drugs solution(dexmedetomidine and remifentanil) of this study will be prepared in 20 ml syringes that are equal in shape will be made by only person who aware of study's groups .Anesthesiologist, patients, all medical stuffs who will collaborated in the study will not aware of patients groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 60 patients who will candidate for direct laryngoscopy will be enrolled. Exclusion criteria: Patients with history of ischemic heart disease; heart failure; asthma; renal failure; hepatic failure; emergency cases and who are morbidly obese will exclude from study.

Intervention groups

Patients in group A will be received an IV infusion of dexmedetomidine 1 mcg/Kg over five minutes with a 20 ml syringe with the label A and patients in group B will be received an IV infusion of remifentanyl 1 mcg/Kg over five minutes with a 20 ml syringe with the label B.

Main outcome variables

Intraoperative hemodynamic, and postoperative respiratory depression, sedation score, postoperative pain and nausea& vomiting will record .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121204011662N13**
Registration date: **2020-02-17, 1398/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-17, 1398/11/28**
Update count: **0**

Registration date

2020-02-17, 1398/11/28

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Dexmedetomidine and Remifentanil in the Anesthesia for Direct Laryngoscopy: A Randomized Clinical Trial

Public title
Comparison of quality anesthesia of two anesthetic drugs in direct laryngoscopy.

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who will candidate for direct laparoscopy under general anesthesia will be enrolled.

Exclusion criteria:
Patients with history of ischemic heart disease Patients with history of heart failure Patients with history of asthma Patients with history of renal failure Patients with history of hepatic failure Patients who are morbidly obese Patients in emergency situation

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly allocated into two groups A & B, according to randomization numbers table using quadratic permutation blocks that will derive from randomization.org.

Blinding (investigator's opinion)
Double blinded

Blinding description
For blindness, All of the drugs solution(dexmedetomidine and remifentanil) of this study will be prepared in 20 ml syringes that are similar and equal in shape , by a nurse of anesthesia who aware of patients' study's groups.These syringes will have label A or B. Anesthesiologist who will use these syringes will not aware of the content of this syringes, just use syringes with label A for patients in group A and syringes with label B for patients in group B. Patients and all medical stuffs who will collaborate in data gathering , will not aware of the content of this syringes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz Medical School

Street address
3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City
Shiraz

Province
Fars

Postal code
197871345

Approval date
2019-12-16, 1398/09/25

Ethics committee reference number
IR.SUMS.MED.REC.1398.519

Health conditions studied

1

Description of health condition studied
Survey of anesthesia for direct laryngoscopy.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Mean arterial blood pressure (MAP)

Timepoint
Values will record at baseline, 5, 10, 15, 30, and 45, minutes.

Method of measurement
Non invasive blood pressure monitoring.

2

Description
Heart rate per minute

Timepoint
Values will record at baseline, 5, 10, 15, 30, and 45, minutes.

Method of measurement
Electrocardiogram

Secondary outcomes

1

Description
Sedation Score

Timepoint
Every 15 minutes in recovery room.
Method of measurement
Ramsay Scale

2

Description
Attacks of respiratory depression
Timepoint
Every 15 minutes in recovery room.
Method of measurement
Defined as a respiratory rate < 8 breaths/min.

3

Description
Incidence of nausea and vomiting
Timepoint
Every 15 minutes in recovery room.
Method of measurement
0: No nausea and vomiting, 1: Nuasea without Vomiting, 2: Both Nausea and Vomiting.

4

Description
Severity of postoperative pain
Timepoint
Every 15 minutes in recovery room.
Method of measurement
Visual analogue Scale

Intervention groups

1

Description
Intervention group 1: After induction of anesthesia,patients in group Awill be received an IV infusion of dexmedetomidine 1 mcg/Kg over five minutes with a 20 ml syringe with the label A.
Category
Treatment - Drugs

2

Description
Intervention group 2: After induction of anesthesia,patients in group B will be received an IV infusion of remifentanyl 1 mcg/Kg over five minutes with a 20 ml syringe with the label B.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalili training and medical center
Full name of responsible person
Mohamma Ali Sahmeddini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
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Fax
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Email
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Web page address
http://research.sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
MohammadAli Sahmeddini
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available