

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

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

Protocol summary

Study aim

We aim to compare the effect of dexmedetomidine with remifentanyl 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 remifentanyl) 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 Remifentanyl 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 remifentanyl) 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.

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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: Nausea 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 A will 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**

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Full name of responsible person

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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

Anesthesiology

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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