

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparative study of the effect of dexmedetomidine and remifentanyl on the quality of endotracheal intubation with videolaryngoscope in patients with neck trauma

Protocol summary

Study aim

Determining the effect of sedation under the influence of dexmedetomidine and remifentanyl during endotracheal intubation with videolaryngoscope glideoscope in patients with neck trauma

Design

Study groups include dexmedetomidine group and remifentanyl group Block randomization with random allocation The sample size is 80 people Trial phase is 3

Settings and conduct

The present study is a randomized controlled clinical trial study on patients who referred to Al-Zahra Hospital due to neck trauma after approval of the plan. The neck was selected in Al-Zahra Hospital and Hospital of Isfahan and after making sure that the NPO was 8 hours, the patients were randomly divided into two groups R and D through Random Allocation software.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Age 60-18 years of both sexes 2- Candidate for neck surgery following neck trauma 3- ASA class 1 and 2 4- Conscious satisfaction 5- Mallampati class 1 to 3 6- BMI less than 30 7- Do not use sedatives and opioids 8- Do not use beta blocker Exclusion criteria 1- Inability to intubate the patient 2- Drug allergy during injection 3- Failure to complete the consent form

Intervention groups

In the dexmedetomidine group, 2 cc of dexmedetomidine equivalent to 200 µg in a 50 cc syringe is mixed with 0.9% normal saline at a rate of 1 g / kgµ1 for 10 minutes as loading and then at a dose of 0.5 g / kg / hµ in maintenance Remifentanyl group, 2 mg remifentanyl mixed with 48 cc normal saline 0.9% and loaded with a loading dose of 0.75 g / kgµ75 for 10 minutes and then 0.1 g / kg / minµ is prescribed as maintenance.

Main outcome variables

Time required for intubation, heart rate, systolic blood

pressure, diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220307054213N1**

Registration date: **2022-05-26, 1401/03/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-26, 1401/03/05**

Update count: **0**

Registration date

2022-05-26, 1401/03/05

Registrant information

Name

Sajad Opera

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 2419

Email address

sajad.op.2014@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-19, 1401/01/30

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of dexmedetomidine and remifentanyl on the quality of endotracheal intubation with videolaryngoscope in patients with neck trauma

Public title

Comparative study of the effect of dexmedetomidine and remifentanyl on the quality of endotracheal intubation with videolaryngoscope in patients with neck trauma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-60 years old from both genders candidate for neck neck trauma surgery ASA class 1 or 2 Informed consent malmpathy class 1 to 3 BMI less than 30 non sedative or opioid user non betablocker user

Exclusion criteria:

Inability to intubating the patient

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random blocks (blocks of 4) are divided into 2 groups of intervention and control. Randomization tool is random allocation. People are randomly divided into two groups, ie it is not known in advance which patient in which group Is utilizing random tool maker

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and health care providers and individuals in the role of data collection are blind to the study, ie the patient does not know which group he is in. The physician in charge of intubation also does not know what part the patient is anesthetized with.the collector of data is also blind to the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isafahan university of medical sciences

Street address

Hezarjarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-03-06, 1400/12/15

Ethics committee reference number

IR.MUI.MED.REC.1400.833

Health conditions studied**1****Description of health condition studied**

Intratracheal intubation with videolaryngoscope in patients with neck trauma

ICD-10 code

XIX

ICD-10 code description

Injury, poisoning and certain other consequences of external causes

Primary outcomes**1****Description**

time needed to intubation

Timepoint

At the beginning of intervention

Method of measurement

Stopwatch

2**Description**

number of successful intubation

Timepoint

at the beginning of intervention

Method of measurement

Counting

3**Description**

systolic blood pressure

Timepoint

0,1,3,5,10,15 minutes after intervention

Method of measurement

manometer

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: group anesthetized by dexmedetomidine 2 cc of dexmedetomidine equivalent to 200 µg in a 50 cc syringe is mixed with 0.9% normal saline 48 and injected at a rate of 1 g / kg for 10 minutes as loading and then at a dose of 0.5 g / kg / h. Main brand Not intended.

Category

Treatment - Drugs

2**Description**

Intervention group: group anesthetized by remifentanyl. 2 mg remifentanyl with 0.48% cc normal saline is administered at a loading dose of 0.75 µg / kg for 10 minutes and then 0.1 g / kg / min as maintenance. No brand is intended.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital Isfahan University of Medical Sciences

Full name of responsible person

دکتر مهرداد مسعودی فر

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Siavash dastjerdi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Mehrdad Masoudifar

Position

Associate Professor of Anesthesiology

Latest degree

Specialist

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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Information about key variables can be shared after being unidentified

When the data will become available and for how long

after finishing the project

To whom data/document is available

All researchers in academic institutions

Under which criteria data/document could be used

For further review of the published article

From where data/document is obtainable

Send request to email masoudifar@med.mui.ac.ir

What processes are involved for a request to access data/document

Will be sent as soon as the person requests

Comments