

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of Dexmedetomidine as local anesthetic adjuvant on sedation and hemodynamic status of patients during fiberoptic nasotracheal intubation

Protocol summary

Summary

(1) Objectives: To evaluate the efficacy of adjuvant dexmedetomidine in airways blocks in fiberoptic intubation facilitation and hemodynamics status, 2) Design: The study population: Patients admitted to hospital's operating room of Imam Hussein (AS) Hospital; Group : Patients were randomly divided into 3 groups: control group , IV Dex group:patients reciving intravenous infusion of dexmedetomidine before blocks. Local Dex group: dexmedetomidine is added to lidocaine used for blocks. Sample size: 96 patients, male or femal. Blinding: double-blind study. (3) Setting and conduct :After obtaining the informed consent, 96 patients entered this double-blind study and randomly divided into 3 groups: the control group, IV Dex group: reciving intravenous infusion of dexmedetomidine before blocks. Local Dex group: dexmedetomidine is added to lidocaine used for blocks. After blocking recurrent laryngeal nerve, superior laryngeal nerves and glossopharyngeal nervs and nasal cavity preparation, propofol infusion(50 microgram per kilogram of body weight per minute) starts to reach Cerebral State Index = 75 .Then fiberoptic intubation is attempted. After securing the airway, induction of general anesthesia is carried out; (4) Participants:patients with indications for awake intubation, 18 to 65 years old, male or female, candidate for elective surgery; (5) Interventions :airway nerve blocks in all patients by lidocaine (dosag:5 mg per kg of body weight). In Local Dex group, dexmedetomidine is added to lidocaine used for blocks (one microgram per kilogram Body weight) is done. In IV Dex group the patient recives one microgram per kilogram of body weight intravenous infusion of dexmedetomidine over ten minutes before blocking the nerves. (6) The main outcome variables: Primary outcome: consumption of propofol, secondary outcomes: 4 criteria used to assess airway blocks: cough, the vocal cords, tolerance during

intubation, tolerance after intubation.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015101224493N1**

Registration date: **2016-01-25, 1394/11/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Parissa Sezari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Clinical Research Developmental Unit, Imam Hossein Medical and educational Hospital, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of Dexmedetomidine as local anesthetic adjuvant on sedation and hemodynamic status of patients during fiberoptic nasotracheal intubation

Public title

Local dexmedetomidine in awake fiberoptic intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-66 year old; ASA class 1 or 2; elective surgery; probable difficult airway; probable injury to cervical spine Exclusion criteria: ASA >3; history of any cardiac disease; history of hypertension; history of renal function impairment; history of liver function impairment; history of opioid/recreational drug abuse; using anti hypertension drugs; using alpha adrenergic agonists or antagonists; history of any psychological disorders; pregnancy; NPO time less than 8 hours for solid food and less than 3 hours for clear fluids; baseline heart rate less than 60 beats per minute; emergent/urgent surgeries; overt coagulopathy or impaired coagulation tests; history of diabetes mellitus

Age

From **18 years** old to **66 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Other

Other design features

Random Number Table

Secondary Ids

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Koudakyar steet, Daneshgah square, Velenjak, Tehran, Iran

City

Tehran

Postal code**Approval date**

2015-09-22, 1394/06/31

Ethics committee reference number

IR.SBMU.SM.REC.1394.42

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

the quality of awake fiberoptic intubation

ICD-10 code

-

ICD-10 code description

-

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

propofol consumption (milligrams per kilogram of body weight)

Timepoint

at the time of reaching CSI score=75

Method of measurement

observation

Secondary outcomes**1****Description**

intubation scores

Timepoint

at the time of bronchoscopy and intubation

Method of measurement

observation

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

Control group: airway nerve blocks by lidocaine (5 milligram per kilogram of body weight) and infusion of 20 cc normal saline over 10 minutes before the blocks

Category

Treatment - Drugs

2

Description

DEX LOCAL group: infusion of 20 cc normal saline over 10 minutes before the above procedures, and 1 microgram per kilogram of body weight dexmedetomidine (Hospira, USA) added to the total volume of lidocaine (5 milligram per kilogram of body weight) used in blocks as an adjuvant .

Category

Treatment - Drugs

3

Description

DEX IV group: intravenous infusion of 1 microgram per kilogram of body weight dexmedetomidine (Hospira, USA) in a 20 cc syringe over 10 minutes before blocks, airway nerve blocks by lidocaine (5 milligram per kilogram of body weight)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Parisa Sezari

Street address

Imam Hossein Hospital , Nezam-abad street, Tehran

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Clinical Research Developmental Unit, Imam Hossein Medical and educational Hospital, Shahid Beheshti

Full name of responsible person

Razavi Moghadam, MD

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Imam Hossein Hospital , Nezam-abad street, Tehran

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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

Clinical Research Developmental Unit, Imam Hossein Medical and educational Hospital, Shahid Beheshti

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

Shahid Beheshti University of MedicalSciences

Full name of responsible person

Parisa Sezari MD

Position

anesthesiology resident

Other areas of specialty/work

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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