Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Studying the effect of Dexmedetomidine as local anesthetic adjuvant on sedation and hemodynami 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

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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 hemodynami 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 opiod/recreational drug abuse; using anti hypertension drugs; usig 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 Sḥahid Beheshti University of Medical Sciences
Street address
Koudakyar steet, Daneshgah square, Velenjak, Tehran, Iran
City
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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 kilgram of body weight dexmedetomidine (Hospira, USA) added to the total volume of lidocaine (5 miligram 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Clinical Research Developmental Unit, Imam Hossein Medical and educational Hospital, Shahid Behesht
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Tehran
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 Behesht
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

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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