# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**


**Name**
Parissa Sezari
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
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Iran (Islamic Republic of)
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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**
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 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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Imam Hossein Hospital , Nezam-abad street, Tehran
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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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**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*