

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of safety and efficacy of two doses of Dexmedetomidine in reducing the incidence of cough after endotracheal tube removal in a patient undergoing elective surgery

Protocol summary

Study aim

Determining and comparing the safety and efficacy of two different doses of dexmedetomidine in reducing the incidence of cough after endotracheal tube removal in a patient undergoing elective surgery

Design

Clinical trial with control group, with parallel, non-blind, non-random groups

Settings and conduct

Study place: Al-Zahra Hospital, Isfahan. Type of blinding: Not blinded Methods: It will be used on three groups of 60 candidates for elective surgery in Al-Zahra Hospital. In doses of one microgram and a half micrograms per kilogram and the control group with 100 ml of normal saline will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Candidates for elective surgery
Age range 60-18 years and with ASA was class 1 and 2.
Patient consent to participate in the study
Criteria for not entering: History of allergy to alpha adrenergic drugs
Liver patients
History of bradycardia
Block av grade 2 or 3
Vascular problems
low blood pressure.
Hypovolemia.
Vasodilator use.
Addicted people.
smoker
Patients with airway infection or history of airway surgery ,
Asthma sufferers.
Those at risk for increased intracranial pressure and intraocular pressure.
Use of antihypertensive drugs or digoxin and GABA pentin.

Intervention groups

Intervention 1: Dexmedetomidine 1mcg / kg diluted in 100 ml of normal saline. Second intervention: Dexmedetomidine 0.5 mce / kg diluted in 100 ml of normal saline. Control group: 100 ml of normal saline.

Main outcome variables

Cough, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, heart rate, oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N19**

Registration date: **2021-09-16, 1400/06/25**

Registration timing: **retrospective**

Last update: **2021-09-16, 1400/06/25**

Update count: **0**

Registration date

2021-09-16, 1400/06/25

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

hamidshetabi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of safety and efficacy of two doses of Dexmedetomidine in reducing the incidence of cough after endotracheal tube removal in a patient undergoing elective surgery

Public title

The effect of dexmedetomidine on reducing the incidence of cough after extubation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are candidates for elective surgery Age range is 18-60 years and with ASA class 1 and 2. Patient consent to participate in the study

Exclusion criteria:

History of allergy to Alpha adrenergic drugs Liver patients Patients with a history of Bradycardia Vascular problems Hypotension Vasodilator use Hypovolemia People who are at risk for increased intracranial pressure or intraocular pressure Addicted people or Smokers People with asthma Patients with a history of airway infection or history of airway surgery.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **540**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Blvd, Isfahan University of Medical Science

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-01-17, 1399/10/28

Ethics committee reference number

IR.MUI.MED.REC.1399.954

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

Tracheal Extubation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Systolic bBlood Pressure

Timepoint

Before Extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Barometer

2**Description**

Diastolic blood pressure

Timepoint

Before Extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Barometer

3**Description**

Pulse rate

Timepoint

Before Extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Pulse oximetry

4**Description**

Oxygen saturation percentage

Timepoint

Before Extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Pulse oximetry

5

Description

Mean arterial pressure

Timepoint

Before Extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Barometer

6

Description

Cough

Timepoint

1, 3, 5 and 10 minutes after the end of the extubation

Method of measurement

View

Secondary outcomes

1

Description

Duration of staying in recovery

Timepoint

Based on minutes from arrival to reaching the modified aldrete score of 9

Method of measurement

Information collection form

2

Description

Adverse airway response

Timepoint

During the time of staying in recovery

Method of measurement

Information collection form

3

Description

Hemodynamic complications

Timepoint

During the time of staying in recovery

Method of measurement

Information collection form

4

Description

Duration of extubation

Timepoint

Based on minutes from the time of discontinuing anesthetic to the time of extubation

Method of measurement

Information collection form

Intervention groups

1

Description

Intervention group 1: In this group, the syringe containing dexmedetomidine (from Behestan Daroo company) is diluted to 1mcg / kg in 100 ml of normal saline and infused into the patient within ten minutes.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, the syringe containing dexmedetomidine (from Behestan Daroo company) is diluted at the rate of 0.5mcg / kg in 100 ml of normal saline and is infused into the patient within ten minutes.

Category

Treatment - Drugs

3

Description

Control group: In this group, the syringe containing 100 ml of normal saline is infused into the patient within 10 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Hamidreza Shetabi

Street address

AL-zahra hospital; Sofe boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 8138

Email

hamidshetabi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghju Javanmard

Street address

Vice chancellor of research and technology of

university. Isfahan university of medical science.
Hezarjirib St.

City

Isfahan

Province

Isfahan

Postal code

7346181746

Email

Research@mui.ac.ir

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

Hamidreza Shetabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

AL-zahra hospital; Sofe boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+980313622020

Email

hamidshetabi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

AL-zahra hospital; Sofe boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+980313622020

Email

hamidshetabi@med.mui.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

AL-zahra hospital; Sofe boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+980313622020

Email

hamidshetabi@med.mui.ac.ir

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

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to

make this available

Title and more details about the data/document

Unidentifiable individual data of participants including hemodynamic indicators and complications can be shared in all three groups.

When the data will become available and for how long

6 month after publication of paper

To whom data/document is available

Academic and medical researcher

Under which criteria data/document could be used

Use for research and treatment purpose

From where data/document is obtainable

Email of person in charge of public accountability ,Dr Hamidreza Shetabi: hamidshetabi@med.mui.ac.ir

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

After the request, it will be sent by email, if possible, within a maximum of one month.

Comments