

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Assessment of dexmedetomidine effect on cough prevention after anesthesia in patients undergoing thyroidectomy

Protocol summary

Study aim

Assessment of dexmedetomidine effect on cough prevention after anesthesia in patients undergoing thyroidectomy

Design

Patients will be divided into intervention and control groups by their number being even or odd when entering the study. The intervention group will receive 0.5 µg / kg dexmedetomidine during anesthesia. Prodrugs will include midazolam 1-2 mg IV and fentanyl 2 µg / kg in both groups. Anesthesia will be induced with propofol 1.5 mg / kg. After confirmation of adequate muscle relaxation by administering atracurium 0.5 mg / kg IV, an endotracheal tube (ETT) with an internal diameter of 7 mm (female) or 8 mm (male) will be inserted into the trachea. The frequency of cough and the severity of cough in both groups will be evaluated and evaluated analogously during recovery and during attendance in recovery. In this study, the severity of cough will be as follows. 0: No cough, 1: One cough, 2: More than one cough, 3: Repeated coughs with lifting of the head

Settings and conduct

The study will be performed to evaluate the effect of dexmedetomidine on patients' cough after thyroidectomy. The study will be performed in the operating room of Imam Khomeini Hospital in Urmia by intervention method in two groups of 35 people as intervention and control. Blinding and randomization were not observed in the study.

Participants/Inclusion and exclusion criteria

Admission requirements: Candidate for thyroidectomy, age 18 to 68 years
Withdrawal conditions: specific diseases such as cancer, smoking, any allergies to vasopressors or local anesthetics, systemic diseases such as cardiovascular, hepatic or renal and pulmonary diseases, including asthma.

Intervention groups

Intervention group: The intervention group consists of 35 people who will use dexmedetomidine during anesthesia.

Control group: includes 35 people who will not use dexmedetomidine during anesthesia.

Main outcome variables

Cough

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211209053338N1**

Registration date: **2021-12-31, 1400/10/10**

Registration timing: **prospective**

Last update: **2021-12-31, 1400/10/10**

Update count: **0**

Registration date

2021-12-31, 1400/10/10

Registrant information

Name

Sonya Mahmoodi Azar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3323 0739

Email address

mahmoodiaza.s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of dexmedetomidine effect on cough prevention after anesthesia in patients undergoing thyroidectomy

Public title

The effect of dexmedetomidine on cough prevention after anesthesia in patients with thyroid surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 68 Candidate for thyroidectomy

Exclusion criteria:

Cancer Chemotherapy Smoking

Age

From **18 years** old to **68 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Urmie University of Medical Sciences

Street address

No. 1, Sero Ave.

City

Urmie

Province

West Azarbaijan

Postal code

5613874758

Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.UMSU.REC.1400.211

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

thyroid disease

ICD-10 code

E07.9

ICD-10 code description

Disorder of thyroid, unspecified

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

Cough

Timepoint

From the moment the patient regains consciousness until 15 minutes later

Method of measurement

Measurement will be through direct vision. The number of coughs will be counted. The severity of cough is as follows: 0: no cough, 1: one cough, 2: more than one cough, 3: recurrent coughs with lifting of the head

Secondary outcomes

empty

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

Intervention group: 35 patients will be candidates for thyroidectomy. In addition to routine medications for general anesthesia, these patients will receive 0.5 micrograms per kilogram of dexmedetomidine in the final 10 minutes of surgery.

Category

Treatment - Drugs

2**Description**

Control group: will include 35 patients who are candidates for thyroidectomy. These patients will only receive routine medications for general anesthesia. There is no placebo in this study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Urmia

Full name of responsible person

دکتر سونیا محمودی آذر

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No. 57, Homafar Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saman Fooladi

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Sonya Mahmoodi Azar

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The questionnaires will be made available anonymously and with a file number.

When the data will become available and for how long

After completing the study

To whom data/document is available

University professors

Under which criteria data/document could be used

In order to find out how to work in SPSS file, anonymous questionnaires will only be available with file number.

From where data/document is obtainable

Contact Dr. Sonya Mahmoodi Azar

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

Information is available after contacting Dr. Sonya Mahmoodi Azar and University approval

Comments