

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of hypopharyngeal collapse pattern by DISE maneuver before and after hyoidothyroid suspension surgery in comparison with control in patients with obstructive sleep apnea

Protocol summary

Study aim

Determination and comparison of hypopharyngeal collapse pattern by DISE maneuver before and after hyoidothyroid suspension surgery in comparison with control in patients referred to amiralam hospital clinic

Design

A randomized controlled trial clinical trial using foursquare blocked randomization and double blinds performed on 48 people

Settings and conduct

The evaluation of sleepiness during the day is recorded by the ESS questionnaire and neurocognitive assessment through the Digit Symbol Substitution Test. The severity of snoring is recorded by the VAS of 0-10. Pattern, level and severity of involvement are determined by drug-induced sleep-induced endoscopy (DISE) with propofol drip. Then the surgery plan is determined. The two groups are divided randomly by using the Foursquare blocked randomization. First, tonsillectomy and palatal suspension surgery are performed. Also RF is done. At the end of pharyngeal surgery, the surgeon is told whether to perform a hyoid suspension or not. About two months after surgery, patients undergo type 4 polysomnography to determine AHI. The severity of snoring after surgery is also recorded by VAS. The pattern, movement and collapse of the hypopharyngeal wall are assessed by DISE maneuver during fibroptic and the results are compared with the preoperative one.

Participants/inclusion and exclusion criteria

Inclusion criteria: AHI > 5 in polysomnography with complaint of obstructive sleep apnea symptoms.
Exclusion criteria: BMI > 35; past history of neck or OSA surgeries; metabolic or cardiovascular diseases; cooperative disinclination.

Intervention groups

Performing up 3 surgery with RF in all patients and performing additional hypothyroidism suspension

surgery in the intervention group and not performing it in the control group.

Main outcome variables

Movement and collapse pattern of hypopharyngeal; intensity of snoring

General information

Reason for update

Acronym

DISE

IRCT registration information

IRCT registration number: **IRCT20190602043791N2**

Registration date: **2021-02-11, 1399/11/23**

Registration timing: **prospective**

Last update: **2021-02-11, 1399/11/23**

Update count: **0**

Registration date

2021-02-11, 1399/11/23

Registrant information

Name

Reza Erfanian Azimzadeh Khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6672 7061

Email address

r_erfanian@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of hypopharyngeal collapse pattern by DISE maneuver before and after hyoidothyroid suspension surgery in comparison with control in patients with obstructive sleep apnea

Public title
Comparison of hypopharyngeal collapse pattern by DISE maneuver before and after hyoidothyroid suspension surgery in comparison with control

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 AHI>5 in polysomnography with complaint of obstructive sleep apnea symptoms
Exclusion criteria:
 BMI>35 past history of neck or OSA surgeries metabolic or cardiovascular diseases cooperative disinclination

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization type is blocked randomization. Foursquare blocks of intervention group (A) and control (B) are defined on cards 1-6 (AABB, ABAB, ABBA, BBAA, BABA, BAAB), the cards are placed inside the envelope. Then the cards are selected randomly and then the random string is created from the sequence of selected cards. Patients in the intervention and control group are included in the study according to this sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient does not know whether he is in the intervention or control group, and the outcome assessor does not know whether hyoido-thyroid suspension has been performed for the patient or not.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Vice Chancellor for Research and Technology, Ghods St., Keshavarz Blvd.

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Postal code

1417653761

Approval date

2020-12-07, 1399/09/17

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1399.037

Health conditions studied

1

Description of health condition studied

Obstructive sleep apnea

ICD-10 code

G47.33

ICD-10 code description

Obstructive sleep apnea (adult) (pediatric)

Primary outcomes

1

Description

Hypopnea apnea ratio index(AHI)

Timepoint

Before the study and two months after surgery

Method of measurement

Polysomnography test

Secondary outcomes

1

Description

Intensity of snoring

Timepoint

Before the study and two months after surgery

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: obstructive apnea patients candidate for palatal suspension surgery who, after the end of pharyngeal surgery, the surgeon also performs hyoid suspension in patients in this group.

Category

Treatment - Surgery

2

Description

Control group: patients with obstructive sleep apnea who are candidates for palatal suspension surgery, but after pharyngeal surgery, the surgeon does not perform hyoid suspension in patients in this group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Alam hospital ENT clinic

Full name of responsible person

Reza Erfanian Azimzadeh Khosravi

Street address

Amir Alam hospital ENT clinic, North Sadi St.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Reza Erfanian Azimzadeh Khosravi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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