

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Oropharyngeal - Lingual Exercises on Patients with Primary Snoring in Amiralmomenin's hospital refers.

Protocol summary

Summary

The prospective before - after study to investigate efficacy of oropharyngeal- lingual exercises (OPL exes) on primary snoring (PS) severity. From 20-65 years old patients who are referred to university Amiralmomenin Hospital, Rasht, because of primary snoring after clinical examinations including vital sign, ENT physical examinations, weight, height, neck and abdomen circumference, and history taking about daytime sleepiness, neuromuscular, thyroid, and cardiopulmonary diseases, and about snoring and its severity (from his/her roommate) we will receive a written informed consent for participating in the study. After that, a standard questionnaire about PS and its severity including Visual Analogue Scale (VAS) will be fulfilled by the patient and his/her roommate. Those patients suffering from severe pulmonary diseases; craniofacial malformations; those with regular use of hypnotic medications & severe obstructive nasal disease will not included in the study. Also, those with probability of severe obstructive sleep apnea syndrome (i.e. more than 5 apnea episodes, daytime sleepiness, Body Mass Index more than 30) will not included in the study. The eligible cases will be referred to voice therapy clinic and an expert voice therapist will train the cases OPL exercises in several sessions. These are a 3 set of exercises for soft palate (2 exercises), tongue (4 exercises), and buccal/facial muscles (5 exercises). After assurance from doing the exercises correctly, we will deliver a Compact Disc containing files of the films of the exercises to the patients and frequently call with them for checking the status of performing the exercises and frequent visits at 3-4 weeks intervals until 3 months. The exercises must be done at least 5 days in the week and 30 minutes daily. In every visit, quality of doing the exercises and severity of the exercises will be registered. Those who would not have the compliance of doing the exercises during last 3 months (according to the patients' and their roommates confess or according to the speech therapist

diagnosis with the accuracy of 80% in doing the exercises) and also those who will not fulfill the follow-up visits will be excluded from the study. The severity of the PS will be measured before and one week after the intervention according to the VAS and standard questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101101138N6**

Registration date: **2011-05-24, 1390/03/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-24, 1390/03/03

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Oropharyngeal - Lingual Exercises on Patients with Primary Snoring in Amiralmomenin's hospital refers.

Public title

The Effect of Oropharyngeal - Lingual Exercises on Snoring

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The patients who are 20-65 years old suffering from snoring Exclusion criteria : not suffering from primary snoring; patients suffering from severe pulmonary disease; craniofacial malformations; those with regular use of hypnotic medications; hypothyroidism; positive history of previous stroke; sinusitis; neuromuscular disease; heart failure; Coronary artery disease; severe obstructive nasal disease; Those who would not have the compliance of doing the exercises during last 3 months (according to the patients' and their roommates confess or according to the speech therapist diagnosis with the accuracy of 80% in doing the exercises) and also those who will not fulfill the follow-up visits.

AgeFrom **20 years** old to **65 years** old**Gender**

Both

Phase

2

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

Single

Other design features**Secondary Ids**

empty

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

Ethic committee of Guilan University of Medical Sciences

Street address

Siadati st.

City

Rasht

Postal code**Approval date**

2010-12-11, 1389/09/20

Ethics committee reference number

11937

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

snoring

ICD-10 code

R06.5

ICD-10 code description

Mouth breathing

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

Primary Snoring Severity

Timepoint

before and one week after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

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

The eligible cases will be referred to voice therapy clinic and an expert voice therapist will train the cases oropharyngeal-lingual exercises in several sessions. These are a 3 set of exercises for soft palate (2 exercises), tongue (4 exercises), and buccal/facial muscles (5 exercises). After assurance from doing the exercises correctly, we will deliver a Compact Disc containing files of the films of the exercises to the patients and frequently call with them for checking the status of performing the exercises and frequent visits at 3-4 weeks intervals until 3 months. The exercises must be done at least 5 days in the week and 30 minutes daily. In every visit, quality of doing the exercises and

severity of the exercises will be registered.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Shadman Nemati

Street address

Amiralmomenin Hospital, 17 Shahrivar st.

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences, Vice Chancellor
for Research

Full name of responsible person

Susan Komaii

Street address

Namjou st. - Rasht

City

Rasht

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Guilan University of Medical Sciences, Vice Chancellor for
Research

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

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Position

Assistant professor

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Position

Assistant professor

Other areas of specialty/work

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Fax

Email

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Web page address

Person responsible for updating data

Contact

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