

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The comparative effect of surgery and surgery along with radio-frequency in the improvement of patients with nocturnal snoring in Isfahan, Iran

Protocol summary

2012-04-14, 1391/01/26

Summary

The purpose of this study was to assess the comparative effect of simultaneous uvulopalatopharyngoplasty and Radio-Frequency treatment with surgery alone for reducing of the upper airway obstruction as well as decreasing or eliminating the snoring in affected patients. This randomized clinical trial was conducted during 2009-2010. The inclusion criteria were as follows: existence of indications for surgery such as daytime sleepiness, daily dysfunction, obstructive sleep apnea with an apnea index, hypopnea over 15, patients with snoring and obstructive sleep apnea which have not improved despite the medical treatments and has tonsils with grade III or IV, and the person also agreed to participate in the study. A total number of 46 patients were consecutively assigned into two groups. The first group underwent uvulopalatopharyngoplasty, whereas the second group received Radio-Frequency in addition to uvulopalatopharyngoplasty. The severity of snoring and sleepiness in patients were recorded before and after the surgery in accordance with a checklist, then the obtained results were compared. The Visual Analogue Scale according to the patient's companion idea was used for assessment of the patient snoring status. The Epworth Sleepiness Scale questionnaire was also used to determine the sleepiness.

Registrant information

Name

Asadolah Asadian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Department of Isfahan University of Medical Sciences

Expected recruitment start date

2009-11-05, 1388/08/14

Expected recruitment end date

2011-03-10, 1389/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative effect of surgery and surgery along with radio-frequency in the improvement of patients with nocturnal snoring in Isfahan, Iran

Public title

The effect of adding Radio-frequency to the surgery in snoring treatment

Purpose

Treatment

Inclusion/Exclusion criteria

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204029355N1**

Registration date: **2012-04-14, 1391/01/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

The inclusion criteria: existence of indications for surgery including daytime sleepiness ; daily dysfunction; obstructive sleep apnea with an apnea index; hypopnea over 15; patients with snoring; obstructive sleep apnea which have not improved despite the medical treatments; has tonsils with grade III or IV; the person also agreed to participate in the study.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar-jarib St., Azadi Sq., Isfahan, Iran

City

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Postal code

Approval date

2009-11-04, 1388/08/13

Ethics committee reference number

388391

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

snoring

Timepoint

before and three months after surgery

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

daytime sleepiness

Timepoint

before and three months after surgery

Method of measurement

The Epworth Sleepiness Scale (ESS)

Intervention groups

1

Description

All of the patients in control group were initially tonsillectomy and then mucosa and sub-mucosa of soft palate were debridement and the palatoglossus and palatopharyngeus muscles were preserved as much as possible and the uvula was shortened and the tip of uvula brought out and then the soft palate returned toward the front and top and a portion of the anterior and posterior parts of the tonsils were removed to create more space. The location of the surgery stitches and restored.

Category

Treatment - Surgery

2

Description

All of the patients in interventional group were initially tonsillectomy and then mucosa and sub-mucosa of soft palate were debridement and the palatoglossus and palatopharyngeus muscles were preserved as much as possible and the uvula was shortened and the tip of uvula brought out and then the soft palate returned toward the front and top and a portion of the anterior and posterior parts of the tonsils were removed to create more space. The location of the surgery stitches and restored and then RF was done in the remaining parts. RF settings were based on individuals' anatomy. Power setting for soft palate in 5 points with regular intervals at the center of soft palate was 12 W. With 12 W of power RF in 6 to 8 points with a distance of one cm for base of tongue was used depending on the size of it. With 15 W of power RF was used for inferior turbinate in superior, posterior and lateral directions with a distance of one cm from each other.

Category

Treatment - Drugs

Isfahan University of Medical Sciences, Hezar-jarib St.,
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Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra University Hospital

Full name of responsible person

Dr Asadolah Asadian

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Department of Isfahan university of Medical
Sciences

Full name of responsible person

Dr Taleb Azarm

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Research Department, Isfahan University of Medical
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City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Department of Isfahan university of Medical
Sciences

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

Isfahan University of Medical Sciences

Full name of responsible person

Dr S.Soheilipour

Position

Associated Professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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