

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Clinical trial to compare pulmonary function tests before and after adenotonsillectomy in adenotonsillar hypertrophy

Protocol summary

Summary

Objective: Adenotonsillar hypertrophy is a common disorder among children without proper treatment may lead to considerable problems. Although the consequences of this disorder have been studied by many researchers, we decided to evaluate the changes of pulmonary function test in these children after adenotonsillectomy and also the correlation between clinical and spirometric parameters. Design: We conduct a before- after clinical trial on children with Adenotonsillar hypertrophy in Alzahra Hospital, Isfahan. Forty children with a diagnosis of upper airways obstruction due to adenotonsillar hypertrophy enroll in this study. Setting and conduct: Children with co-morbidity and other cause of airways obstruction exclude. Spirometric parameters are gathered and patients will operate for Adenotonsillectomy. Forty days later, patients are called for another spirometry again. In addition, to assess disease severity, symptom score is defined. Finally the pre and post procedure parameters are analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508176699N2**

Registration date: **2015-10-18, 1394/07/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-18, 1394/07/26

Registrant information

Name

Mehrdad Rogha

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to compare pulmonary function tests before and after adenotonsillectomy in adenotonsillar hypertrophy

Public title

Pulmonary Tests After Adenotonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All children presented enlarged tonsils i.e. hypertrophy more than 2 +/ (degrees III and IV), according to Brodsky classification will be enrolled.

Exclusion criteria: Patients with cardiopulmonary diseases, neurological involvement, obese children (BMI more than 30 kg/m²), those with other causes of nasal obstruction such as polyps, nasal septal deviations and

thoracic skeletal deformity will be excluded.

Age
From **5 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan

City
Isfahan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
388441

Health conditions studied

1

Description of health condition studied
Enlargement of tonsils

ICD-10 code
J35.1

ICD-10 code description
Hypertrophy of tonsils

2

Description of health condition studied
Enlargement of adenoids

ICD-10 code
J35.2

ICD-10 code description

Hypertrophy of adenoid

Primary outcomes

1

Description
spirometric factors

Timepoint
preoperation and 40 days after it

Method of measurement
spirometry

Secondary outcomes

empty

Intervention groups

1

Description
Adenotonsillectomy in rose position and by sharp dissection method is done.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital, Isfahan

Full name of responsible person

Street address

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person
Mehdi nematbakhsh

Street address
Isfahan University of Medical Sciences, Hezarjarib Av., Isfahan, Iran

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source

Vice chancellor for research, 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

Zhale Amini,MD

Position

Otolaryngology Resident

Other areas of specialty/work

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ENT department, Alzahra hospital, Soffeh Av.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

MOSTAFA RAISI

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

Web page address

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