

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparision of Adenidectomy versus Adenotonsillectomy on changing in symptoms in pediatric patients with chronic rhinosinosis

Protocol summary

2012-09-07, 1391/06/17

Summary

The purpose of this study is to assess the efficacy of adenotonsillectomy comparing with adenoidectomy for treatment of symptoms and signs caused by chronic sinusitis. sixty-under the age of 14 years- subjects with chronic sinusitis were recruited from patients referred to otolaryngology clinic, Besat hospital Hamedan University of Medical Science. symptoms and signs of this patient include purulent discharge, facial pain, post nasal purulent discharge, cough, halitosis and bilateral maxillary mucosal thickening in water's view radiography. symptoms and signs of patient did not improved with medical therapy (oral antibiotic & anti allergy for at least 4 weeks). the baseline subject symptoms perception was assessed using visual analogue scale before the intervention. children randomly divided into 2 groups and in one group adenoidectomy and in another adenotonsillectomy was performed. all children discharge from hospital in second day after surgery. all children had the same antibiotics and nutrition and nursing a week after surgery. in twenty eight day after surgery water's view radiography is performed and clinical signs and symptoms by person is informed of the child's medical & surgical history will be recorded in check list. finally the efficacy of adenotonsillectomy & adenoidectomy by comparing the check lists is evaluated

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Hamedan university of medical Sciences and health services

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of Adenidectomy versus Adenotonsillectomy on changing in symptoms in pediatric patients with chronic rhinosinosis

Public title

Comparision of Adenidectomy versus Adenotonsillectomy on changing in symptoms in patients less than 14 years old with chronic rhinosinosis

Purpose

Treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081810409N3**

Registration date: **2012-09-07, 1391/06/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Inclusion/Exclusion criteria

inclusion criteria: children -under the age of 14 years- subjects with chronic sinusitis were recruited from patients referred to otolaryngology clinic, Besat hospital Hamedan University of Medical Science. symptoms and signs of this patient include purulent discharge, facial pain, post nasal purulent discharge, cough, halitosis and bilateral maxillary mucosal thickening in water's view radiography. symptoms and signs of patient did not improved with medical therapy (oral antibiotic & anti allergy for at least 4 weeks). exclusion criteria: 1- children with chronic sinusitis with tonsil size and grade have less than 2- tonsils occupy less than 25% of their oropharyngeal space - 2- patient with systemic diseases such as diabetes, anemia, immunodeficiency, nasal polyposis ,...

Age

To 14 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Science

Street address

Fahmide str, Hamedan

City

Hamedan

Postal code

Approval date

2012-07-03, 1391/04/13

Ethics committee reference number

16/35/9/1217/د/پ

Health conditions studied

1

Description of health condition studied

Chronic Rhinosinusitis

ICD-10 code

J32.9

ICD-10 code description

Chronic sinusitis, unspecified

Primary outcomes

1

Description

Nasal Obstruction/Blocage

Timepoint

Before surgery-one month after surgery

Method of measurement

visual analogue scale

2

Description

halitosis

Timepoint

Before surgery-one month after surgery

Method of measurement

visual analogue scale

3

Description

facial pain/pressure

Timepoint

Before surgery-one month after surgery

Method of measurement

visual analogue scale

4

Description

nasal discharge

Timepoint

Before surgery-one month after surgery

Method of measurement

visual analogue scale

5

Description

posterior drainage

Timepoint

Before surgery-one month after surgery

Method of measurement

visual analogue scale

6

Description

cough

Timepoint

Before surgery-one month after surgery

Method of measurement

visual analogue scale

7

Description

waters view radiography

Timepoint

Before surgery-one month after surgery

Method of measurement

Questionare

Secondary outcomes

empty

Intervention groups

1

Description

adenoidectomy surgery

Category

Treatment - Surgery

2

Description

adenotonsillectomy surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

DR Mohammad Ahmadi-assistant of otolaryngology

Street address

Motahhari ave, Hamedan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Meical Science

Full name of responsible person

Dr Hoseyn Emadmomtaz

Street address

Fahmide str, Hamedan

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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

Hamedan University of Meical Science

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

Hamedan University of Meical Science

Full name of responsible person

Dr Mohammad Ahmadi

Position

ASSISTANT OF OTOLARYNGOLOGY

Other areas of specialty/work

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Contact

Name of organization / entity

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Full name of responsible person

Dr Fatollah Behnood

Position

Associate Professor of otolaryngology

Other areas of specialty/work

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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