

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of Adenoidectomy/Tonsillectomy Effects on Cardiac Function of Children

Protocol summary

Summary

Adenotonsillar hypertrophy is one of the most common diseases of the upper airways, which can lead to cardiopulmonary complications and the contraction of the pulmonary artery that leads pulmonary artery hypertension. Therefore, in this study, we intend to evaluate the changes in right ventricular function in children undergoing Adenotonsillectomy surgery by echocardiography. In this study, 42 children under the age of 11 with adenotonsillar hypertrophy, which are adenotonsillectomy surgical candidates due to obstructive issues, were selected and children with signs such as infection secondary to tonsillar Hypertrophy, obstruction of upper airways, etc were excluded. Before surgery using echocardiography by paediatric cardiologist, heart function, including blood pressure and heart rate, mean pressure of right pulmonary artery Myocardial Performance Index, Mid Pulmonary Artery Pressure and other cardiac parameters related to the child's heart is measured, and the process will be repeated three months after the operation and parameter changes measured in this period will be analysed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503301138N16**

Registration date: **2015-06-04, 1394/03/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-04, 1394/03/14

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Science, Vice Chancellor for Research

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Adenoidectomy/Tonsillectomy Effects on Cardiac Function of Children

Public title

Study of Adenoidectomy/Tonsillectomy Effects on Cardiac Function of Children with Adenotonsillar Hypertrophy According to Echocardiographic Parameters in Amiralmomenin Hospital, Rasht -2015

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: parental consent for children to participate in the study no underlying heart disease;

surgical indications of adenotonsilectomy surgery; no lung disease; adenotonsillar hypertrophy of grade III and IV; Exclusion criteria: patients with infectious symptoms secondary to adenotonsillar hypertrophy; obstruction of upper airways secondary to obstructive agents except for adenotonsillar hypertrophy; septum deviations. subglottic stenosis; stenosis secondary to previous surgeries

Age

To **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

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**

Guilan University of Medical Sciences

Street address

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Postal code

4139637459

Approval date

2015-04-27, 1394/02/07

Ethics committee reference number

GUMS.REC.1394.12

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

Hypertrophy of adenotonsil

ICD-10 code

J35.3

ICD-10 code description

Hypertrophy of tonsils with hypertrophy of adenoids

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

EKG

Timepoint

Before surgery and three months after surgery

Method of measurement

echocardiography

2**Description**

ECG of blood pressure

Timepoint

Before surgery and three months after surgery

Method of measurement

GE echocardiography machine

3**Description**

Heart rate

Timepoint

Before surgery and three months after surgery

Method of measurement

GE echocardiography machine

4**Description**

Mean pulmonary artery pressure

Timepoint

Before surgery and three months after surgery

Method of measurement

GE echocardiography machine

5**Description**

Myocardial Performance

Timepoint

Before surgery and three months after surgery

Method of measurement

GE echocardiography machine

6**Description**

Mid Pulmonary Artery Pressure

Timepoint

Before surgery and three months after surgery

Method of measurement

GE echocardiography machine

Secondary outcomes

empty

Intervention groups

1

Description

implementation echocardiography and electrocardiography, before and after surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralamomenin Hospital

Full name of responsible person

Dr Rahmatolah Banan

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Science, Vice Chancellor for Research

Full name of responsible person

Susan Komaee

Street address

Namjou St

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 Science, 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 Rahmatollah Banan

Position

Professor

Other areas of specialty/work

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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