Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of Adenoidectomy/Tonsillectomy Effects on Cardiac Function of Children

Protocol summary

Summary

Adenotonsilar 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 adenotonsilar hypertrophy, which are adenotonsillectomy surgical candidates due to obstructive issues,were selected and children with signs such as infection secondary to tonsilar 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 Pulmunary 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
+98 13 1223 8307
Email address
entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source
Guilan University of Medical Science, Vice Chancellor for Resarch

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 Adenotonsilar 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; adenotonsilar hypertrophy of grade III and IV; Exclusion criteria: patients with infectious symptoms secondary to adenotonsilar hypertrophy; obstruction of upper airways secondary to obstructive agents except for adenotonsilar 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 Pulmunary 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 electro cardiography, 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 Resarch
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 Resarch
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
Street address
Amiralamomenin Hospital, 17 shahrivar St
City
Rasht
Postal code
4139637459
Phone
+98 13 3322 5242
Fax
Email
banan@gums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Amiralamomenin Hospital, 17 shahrivar St
City
Rasht
Postal code
4139637459
Phone
+98 13 3322 5242
Fax
Email
banan@gums.ac.ir
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