

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The evaluation of administering oral antibiotics after tonsillectomy on surgery's complications in patients

Protocol summary

Study aim

Comparison of pain, bleeding, fever and time to return to diet after tonsillectomy between the group who receive antibiotic and who don't

Design

Patients will undergo tonsillectomy and randomly divided in to two groups of control and intervention. Intervention group will get antibiotics (amoxicillin 40 mg/kg) after surgery and control group won't. They will be asked to come 7 days and 2 weeks later to follow up and filling check lists (single blinded). Sample size is 100 . In this study, a randomized block method was used.

Settings and conduct

100 patients with inclusion criteria referring to ENT office in Alzahra hospital, were chosen and after explaining the possible complications of not getting antibiotics they will fill consent forms. Patients will undergo tonsillectomy and randomly divided in to two groups of control and intervention. Intervention group will get antibiotics (amoxicillin 40 mg/kg) after surgery and control group won't. They will be asked to come 7 days and 2 weeks later to follow up and filling check lists. The trial is one sided blinded and patients are blinded and group allocation was concealed by assigning a unique code to each participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: common signs of adenotonsillar hypertrophy. Exclusion criteria: sensitivity to antibiotics like penicillin; pharyngitis symptoms; taking antibiotic within 2 weeks before surgery.

Intervention groups

Intervention group: patients who get antibiotic after surgery and control group: patients who don't get antibiotic after surgery.

Main outcome variables

Determination and comparison of pain, bleeding, fever, return time to the main diet after tonsillectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110603006699N4**

Registration date: **2019-05-28, 1398/03/07**

Registration timing: **prospective**

Last update: **2019-05-28, 1398/03/07**

Update count: **0**

Registration date

2019-05-28, 1398/03/07

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

Expected recruitment start date

2019-05-31, 1398/03/10

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of administering oral antibiotics after tonsillectomy on surgery's complications in patients

Public title

Effect of antibiotic on surgery's complication after tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with tonsillectomy indications such as: adenotonsillar hypertrophy, OSA, oral breathing, deformity in head and face development, problem in talking, chronic recurrent tonsillitis, chronic middle ear infection or recurrent acute middle ear infection.

Exclusion criteria:

Sensitivity to antibiotics like penicillin Pharyngitis symptoms Taking antibiotics within 2 weeks before surgery

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be selected according to their referral to the ENT Clinic in this study. Using the random function command of Excell software, random numbers will be assigned to each patient by a person independent of the research team and then he/she prints the numbers on small pieces of paper. Then, the papers will be folded so the page with the numbers could not be seen. After putting the papers into a box, another independent person takes 50 paper pieces from the box and puts them into a section which is known as the Antibiotic group, and the other 50 pieces are put in the section known as the No Antibiotic group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not be informed about the group they are in (control or intervention). Assessors will also be unaware of the patient group. But health care providers, will not be blind due to give Antibiotic to patient

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan university of medical science

Street address

hezar jirib Ave, Isfahan university of medical science

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Province

Isfahan

Postal code

81746-73461

Approval date

2017-05-17, 1396/02/27

Ethics committee reference number

IR.MUI.REC.1396.3.057

Health conditions studied

1

Description of health condition studied

tonsillectomy-antibiotics

ICD-10 code

J35.3

ICD-10 code description

Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description

The amount of pain after tonsillectomy based on the questionnaire

Timepoint

Measurement of pain 1 and 7 days after tonsillectomy

Method of measurement

visual analogue scale

2

Description

The incidence of post-tonsillectomy hemorrhage based on the questionnaire

Timepoint

Measuring the incidence of bleeding 1 and 7 days after the operation of tonsillectomy

Method of measurement

Designed questionnaire

3

Description

The incidence of post-tonsillectomy fever based on the questionnaire

Timepoint

Measuring the incidence of fever 1 and 7 days after the

operation of tonsillectomy
Method of measurement
Designed questionnaire

4

Description

Time to return to regular diet

Timepoint

Measure the time to return to normal diet 14 days after tonsillectomy

Method of measurement

Designed questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: oral amoxicillin is given TDS for one week(40 mg/kg) (Farabi pharmaceutical company)

Category

Treatment - Drugs

2

Description

Control group: The control group does not receive any antibiotics

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Alzahra hospital

Full name of responsible person

Mehrdad Rogha

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Alzahra hospital , Soffeh Blvd , Keshvari Highway , Isfahan , Iran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mehrdad Rogha

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available