

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of different methods of prophylaxis antibiotics on complications after adenotonsillectomy

Protocol summary

Study aim

Determining the effect of different methods of prophylactic antibiotics on complications after adenotonsillectomy

Design

Clinical trial with control group and two intervention groups, parallel group, randomized, phase 2 groups on 58 patients. Sealed envelopes will be used for randomization.

Settings and conduct

The present project will be carried out in Imam Reza and Ghaem Hospitals. It has two intervention groups and a control group. The control group will receive intraoperative cefazolin and postoperative oral amoxicillin. The two intervention groups, once will receive only preoperative injectable cefazolin and the other group will not receive any antibiotics. Patients will be evaluated the day after surgery and one week after, as well as 14 days after surgery.

Participants/Inclusion and exclusion criteria

patients who will refer to Ghaem and Imam Reza Hospital to adenotonsillectomy based on diagnostic studies of obstructive causes and recurrent pharyngitis during the years 1400 to 1401 will be included in the study.

Intervention groups

Two intervention groups, one will receive only preoperative injectable cefazolin and the other group will not receive any antibiotics.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210814052181N1**

Registration date: **2021-08-30, 1400/06/08**

Registration timing: **prospective**

Last update: **2021-08-30, 1400/06/08**

Update count: **0**

Registration date

2021-08-30, 1400/06/08

Registrant information

Name

Javad Salimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2117

Email address

salimij1400@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of different methods of prophylaxis antibiotics on complications after adenotonsillectomy

Public title

Evaluation of the effect of different methods of prophylaxis antibiotics on complications after adenotonsillectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being 5 to 18 years old Informed consent

Exclusion criteria:

Take antibiotics 2 weeks before surgery existence of symptoms of infectious disease before surgery Allergy to penicillin and cefazolin The patient has a defective immune system

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the method of simple randomization is individual and the randomization tool is a sealed envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Qureshi Building, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-06-19, 1400/03/29

Ethics committee reference number

IR.MUMS.REC.1400.055

Health conditions studied

1

Description of health condition studied

Adenotonsillectomy

ICD-10 code

B34.0

ICD-10 code description

Adenovirus infection, unspecified

Primary outcomes

1

Description

pain

Timepoint

after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Only cefazolin will be given preoperatively

Category

Prevention

2

Description

Intervention group2 : No antibiotics will be prescribed

Category

Other

3

Description

Control group: They will receive injectable cefazolin before surgery and oral amoxicillin after surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital and Ghaem Hospital.

Full name of responsible person

Bashir Rasoulia

Street address

Imam Reza Hospital, Taghiabad Square

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9137913316
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Javad Salimi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as information about the main outcome, is shared.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Academic and scientific institutions

Under which criteria data/document could be used

Use in review articles

From where data/document is obtainable

By sending an email to the responsible author

What processes are involved for a request to access data/document

excel

Comments