

# 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)

##### Phone

+98 31 3664 0352

##### Email address

rogha@med.mui.ac.ir

##### 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

##### City

Isfahan

##### 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

**Street address**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3668 5555

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+98 31 3668 4510

**Email**

alzahra@mui.ac.ir

**Web page address**

<http://alzahra.mui.ac.ir>

## Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo Javanmard

**Street address**

Esfahan University of Medical Science , Hezar Jerib street , Isfahan , Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

sh\_haghjoo@med.mui.ac.ir

**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

**Street address**

Kashani Hospital, Kashani Street, Isfahan, Iran

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8183983434

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

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**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Elham Sadat Azimi

**Position**

Physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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elhamazimi72@gmail.com

**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