

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Co-Amoxiclave on post-adenotonsillectomy pain and bleeding

Protocol summary

Summary

Objective of this study is to evaluate the effect of Co-Amoxiclave on post-adenotonsillectomy pain and bleeding. A randomized double blind stage III clinical trial with placebo (control group) in a single center (Shiraz Dastgheib Hospital) will be conducted from February 2012 to February 2014. Oral dosage of 5ml CO-Amoxiclave suspension 457, 312 and 156 in adults and children more than 6 years and children with 3-6 years old, respectively every 8 hours will be administered. The duration of intervention will be one week after surgery. Indication of tonsillectomy in our study will be three or more severe recurrent attacks of tonsillitis within each two consecutive years. Exclusion criteria are: 1- Medical condition requiring pre-operative antibiotics. 2-Antibiotics administered within 1 weak prior to tonsillectomy. 3- History of penicillin allergy. 4- Children less than 3 years old. We will have 150 patients, in two groups (oral antibiotic and placebo). The placebo made by the local pharmacy in Dastgheib Hospital for control group. We consider pain and hemorrhage as the primary outcome, also return time to normal diet, Acetaminophen consumption and fever as secondary outcome. To evaluate post-operative pain, we use Visual analog scale. The attacks of post-tonsillectomy hemorrhage will consider positive when patients refer to hospital and check by ENT specialist. Outcomes will check for seven days after operation. Pain and temperature will be checked four times a day; before breakfast, lunch, dinner and before sleep.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010715496N2**

Registration date: **2014-01-29, 1392/11/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-29, 1392/11/09

Registrant information

Name

Sareh Roosta

Name of organization / entity

Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 5323

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namazi_balini@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2012-02-01, 1390/11/12

Expected recruitment end date

2014-02-28, 1392/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Co-Amoxiclave on post-adenotonsillectomy pain and bleeding

Public title

The effect of Co-Amoxiclave on post-adenotonsillectomy pain and bleeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who undergo tonsillectomy. Indication of tonsillectomy is three or more severe recurrent attacks of tonsillitis within each two consecutive years. Exclusion criteria: medical condition requiring perioperative antibiotics; antibiotics administered within 1 week prior to tonsillectomy; history of penicillin allergy; children less than 3 years old.

Age

From **3 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2007-10-14, 1386/07/22

Ethics committee reference number

CT-86-3653

Health conditions studied

1

Description of health condition studied

Post-adenotonsillectomy pain and bleeding

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-adenotonsillectomy pain

Timepoint

0.5, 1, 2, 4, 8, 16, 24 Hours after adenotonsillectomy and then four times a day; before breakfast, lunch, dinner and also before sleep for 7 days after surgery

Method of measurement

Visual Analog Scale (VAS)

2

Description

Post-adenotonsillectomy hemorrhage

Timepoint

Primary hemorrhage: hemorrhage before 24 hours after operation and secondary hemorrhage: after 24 hours after operation

Method of measurement

Observation by ENT specialist

Secondary outcomes

1

Description

Time to return to the normal diet

Timepoint

Seven days after adenotonsillectomy

Method of measurement

Questionnaire that fills by the patients or their parents

2

Description

Acetaminophen consumption

Timepoint

Seven days after adenotonsillectomy

Method of measurement

Questionnaire that fills by the patients or their parents

3

Description

Fever

Timepoint

Seven days after adenotonsillectomy

Method of measurement

The temperature measured by a nurse at the first 24 hour after surgery and by the educated patients or their parents at 2-7 days after operation that records in the questionnaire.

Intervention groups

1

Description

In intervention group: oral dosage of 5ml CO-Amoxiclave suspension 457 (Amoxicillin 400 mg + Clavulanic Acid 57 mg/5 ml) every 8 hours in adults, 5ml CO-Amoxiclave suspension 312 (Amoxicillin 250 mg + Clavulanic Acid 62.5 mg/5 ml) every 8 hours in children more than 6 years old, and 5ml CO-Amoxiclave suspension 156 (Amoxicillin 125 mg + Clavulanic Acid 31.25 mg/5 ml), in children with 3-6 years old every 8 hours will be administered for one week after tonsillectomy.

Category

Prevention

2

Description

Control group: will receive placebo made by the local pharmacy in Dastgheib Hospital for one week after tonsillectomy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dastgheib hospital

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Otolaryngology, Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Faramarzi

Position

Associate professor of otolaryngology

Other areas of specialty/work

Street address

Khalili Street-Khalili hospital-Department of Otolaryngology

City

Shiraz

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Faramarzi@sums.ac.ir

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Person responsible for updating data

Contact

Name of organization / entity

Center for Development of Clinical Studies of Nemazee hospital- Vice Chancellery of Research and Tec

Full name of responsible person

Sareh Roosta

Position

MSc of biostatistics

Other areas of specialty/work

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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