

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of antibiotic therapy on recovery after tonsillectomy and adenotonsillectomy complications

Protocol summary

Summary

Patients were selected from those admitted in ENT unit of Birjand Vliasr hospital for tonsillectomy and adenotonsillectomy. All patients were examined by an ENT specialist before surgery and then referred to anesthesia clinic for pre-operation evaluation. The conditions for participating in the study were explained for all patients or their guardians and a written consent was obtained if they tended to participate. Participants were randomly divided in two experimental and control groups. Patients were hospitalized in ENT one day before operation while their vital signs, history and physical examination were performed by the ENT specialist. In all patients routine pre-operation tests were done including; CBC diff, B&G Rh PT& PTT, nasopharynx and lateral radiographs, and in patients over 40 years ECG and CXR. The night before surgery patients were NPO for at least 8 hours. In control group serum dextrose water %5 was started as maintenance with a dose of 35 mg/kg body weight in adults and 10 mg/kg body weight in children. In experimental group during the first 24 hours, in addition to serum dextrose water %5, the same dose of ampicillin was used. Patients took ampicillin in IV, 75 mg/kg a dose before surgery and then for 24 hours 1 dose every 6 hours. Next they received 50 mg/kg amoxicillin every 6 hours for a week. After surgery patients took serum until they were able to eat. In the recovery patients were examined by a trained but unaware nurse (who didn't know which group had received antibiotics and which had not) every hour for 4 hours, then every 3 hours in two sessions (up to 10 hours after surgery) and after 24 hours. Bleeding, nausea and vomiting, the start time of drinking liquids, speak status, pain, oral temperature and wound healing were all considered and data was recorded in a questionnaire. Patients were discharged from the hospital after 24 hours and were recommended to refer in any case of complications and intense pain. 7 days after the surgery patients were visited again for evaluation of their improvement and data was recorded.

Both groups received washing with cold NS (normal saline) and the same cold liquid diet.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120211637N1**

Registration date: **2013-02-05, 1391/11/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-05, 1391/11/17

Registrant information

Name

Seyed Hasan Golboie Mousavi

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 1444 0388

Email address

rezamood@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences-research assistant

Expected recruitment start date

2012-11-20, 1391/08/30

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty
Scientific title
Effect of antibiotic therapy on recovery after tonsillectomy and adenotonsillectomy complications

Public title
Effect of antibiotic therapy on recovery after tonsillectomy and adenotonsillectomy complications

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criterion: all patients admitted for tonsillectomy and adenotonsillectomy in ear, nose and throat department Valiasr Hospital, Birjand, Iran. Exclusion criteria: fever (oral temperature greater than 38.2); acute laryngopharyngitis or evidence of systemic infection in the past three weeks; adenoidectomy alone any type of bleeding disorder (pt, ptt abnormal) and throat disorders like laryngeal cleft palate with underlying diseases (heart disease, respiratory ...) or contraindication for general anesthesia, history of peritonsillar abscess, serous otitis media (SOME), evidence of active infection at the time of entry, immunodeficiency, and long-term use of corticosteroids.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **138**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Birjand University of Medical Sciences Ethics Committee
Street address

Birjand University of Medical Sciences, Ghaffari Street
City
Birjand
Postal code
Approval date
2012-11-11, 1391/08/21
Ethics committee reference number
125/85044

Health conditions studied

1

Description of health condition studied

Tonsillectomy

ICD-10 code

28.92

ICD-10 code description

tonsillectomy

2

Description of health condition studied

Adenotonsillectomy

ICD-10 code

28.92

ICD-10 code description

Adenectomy

Primary outcomes

1

Description

postoperative Recovery and complications

Timepoint

from 4 hours after surgery to one week later

Method of measurement

Nausea and vomiting - oral temperature - bleeding - Time to start drinking fluids - pain -analgesia needed after tonsillectomy and adenotonsillectomy r

Secondary outcomes

1

Description

oral temperature

Timepoint

4 hours after operation-10 hours after operation-1 week after operation

Method of measurement

mercury thermometer

2

Description

pain

Timepoint

4 hours after surgery-7 hours after surgery-10 hours after surgery-1 week after surgery

Method of measurement

pain scale Criterion

3

Description

nausea-vommiting

Timepoint

6 hours after surgery

Method of measurement

Rhodes index

4

Description

bleeding

Timepoint

intra operation-24 hours after operation-24 hours later

Method of measurement

a case history

5

Description

White blood cell count

Timepoint

24 hours after operation

Method of measurement

CBC

Intervention groups

1

Description

Ampicillin intravenously as a single dose of 75 mg per kg before surgery and one dose every 6 hours to 24 hours one and for one week amoxiciline capsul 50 mg per kg every 8 hours

Category

Treatment - Drugs

2

Description

The control group did not receive any antibiotics.

Category

Diagnosis

Recruitment centers

1

Recruitment center**Name of recruitment center**

ENTdepartment, Birjand Valiasr hospital

Full name of responsible person

Dr Golboie, ENT specialist

Street address

Ghaffari street- Valiasr hospital

City

Birjand

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Birjand Univercity of Medical Sciences

Full name of responsible person

Dr Asghar Zarban

Street address

Birjand Univercity of Medical Sciences, Ghaffari street

City

Birgand

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Birjand Univercity 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**Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Mofateh

Position

ENT specialist

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Web page address**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