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 adeno-tonsillectomy. 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 Univercity of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Birjand Univercity 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 critria: fever (oral temperature greater than 38.2); acute larengopharngyt 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 Perry tonsilar 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 Univercity of Medical Sciences Ethics Committee

Street address

Birjand Univercity 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 tempreture

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
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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