Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of bipolar electrocautery and cold dissection methods on outcomes of tonsillectomy and adenotonsillectomy

Protocol summary

Summary

This study compared the effects of bipolar electrocautery and cold dissection methods on tonsillectomy and adenotonsillectomy outcomes. This prospective randomized clinical trial study was performed on 500 patients who referred to a specialized ENT clinic with surgery indications. Inclusion criteria were obstruction of upper airway and chronic tonsillitis. Exclusion criteria included a history of tonsillitis within the last three weeks, hemorrhagic diathesis, hematological disorders, congenital malformed tonsils, craniofacial malformations, asymmetric tonsil appearance, neurological disorders, sensitivity to anesthetic drugs, peritonsillar abscess suspected or confirmed tonsillar malignancy, and diabetes. The candidate patients were randomized systematically and operated alternately by bipolar electrocautery and cold dissection methods. The study was double-blind, as neither the data collector nor the patient was aware of the groups. Different variables were assessed such as pain intensity, intraoperative and postoperative blood loss, pain intensity and referred pain in the middle ear, time to start eating after surgery, patient fever, nausea and vomiting, etc.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012911637N2**
Registration date: **2017-03-03, 1395/12/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-03, 1395/12/13

Registrant information

Name

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Name of organization / entity

Birjand Univercity of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery for Research, Birjand University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of bipolar electrocautery and cold dissection methods on outcomes of tonsillectomy and adenotonsillectomy

Public title

Comparison of bipolar electrocautery and cold dissection methods on tonsillectomy and adenotonsillectomy outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with obstructed upper airway; chronic, recurrent tonsillitis; or symptomatic

adenotonsillar hypertrophy. Exclusion criteria: a history of tonsillitis within the last three weeks; hemorrhagic diathesis; hematological disorders; congenital malformed tonsils; craniofacial malformations; asymmetric tonsil appearance; neurological disorders; sensitivity to anesthetic drugs; peritonsillar abscess suspected or confirmed tonsillar malignancy and diabetes

Age
From **7 years** old to **100 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **500**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Birjand University of Medical Sciences

Street address
Ghaffari St.,

City
Birjand,

Postal code

Approval date
2014-11-22, 1393/09/01

Ethics committee reference number
01.09.1393

Health conditions studied

1

Description of health condition studied
local pain

ICD-10 code
R07.0

ICD-10 code description
Pain in throat

2

Description of health condition studied
Pain referred to the middle ear

ICD-10 code
H74.8

ICD-10 code description
Other specified disorders of middle ear and mastoid

3

Description of health condition studied
Fever

ICD-10 code
A68.9

ICD-10 code description
Relapsing fever, unspecified

4

Description of health condition studied
Nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Local pain intensity

Timepoint
During and 24 h after operation

Method of measurement
Visual Analogue Scale

2

Description
Time to re-start eating

Timepoint
after operation

Method of measurement
observation by the nurse

3

Description
Pain referral in the middle ear

Timepoint
Before and 24 h after operation

Method of measurement
Visual Analogue Scale

4

Description
Fever

Timepoint
Before and 24 h after operation

Method of measurement

Thermometer

5

Description
Nausea
Timepoint
Before and 24 h after operation
Method of measurement
Interview by nurse

6

Description
Vomit
Timepoint
Before and 24 h after operation
Method of measurement
Interview by nurse

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group (cold dissection): The patients were operated using cold dissection method. At first, they underwent general anesthesia. Afterwards, using a knife and elevator, the anterior pillar was incised. The tonsils were dissected toward the lower pole. The tonsillar fossa was packed with a swab, and the other tonsil was removed.
Category
Treatment - Surgery

2

Description
Second Intervention Group (Bipolar Electrocauter): The patients were operated by bipolar electrocautery method. First, they underwent general anesthesia. The tonsil was grasped and cut by a cautery pen, and the vessels were burned.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-asr Hospital
Full name of responsible person
Mohammad Reza Mofateh (MD)
Street address
Vali-e-asr Hospital, Ghaffari St.,
City
Birjand,

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research, Birjand University of Medical Sciences
Full name of responsible person
Gholam Reza Sharifzadeh
Street address
Ghaffari St.,
City
Birjand,
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, Birjand 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
Name of organization / entity
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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