

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

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

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

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**

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Reza Mofatteh

Position

Assistant Professor

Other areas of specialty/work**Street address**

Ghaffari St., Vali-e Asr Hospital,

City

Birjand,

Postal code**Phone**

+98 56 3244 3001

Fax**Email**

drmfatfeh@yahoo.com

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

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Reza Mofatteh

Position

Assistant Professor

Other areas of specialty/work**Street address**

Vali-e Asr Hospital, Ghaffari St.,

City

Birjand,

Postal code**Phone**

+98 56 3244 3001

Fax**Email**

drmfatfeh@yahoo.com

Web page address**Street address**

Ghaffari St.,

City

Birjand,

Postal code**Phone**

+98 56 3239 5680

Fax**Email**

hadirooz@gmail.com

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

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

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

Position

PhD Candidate in Translation Studies

Other areas of specialty/work