

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of complication of tonsillectomy by Cold dissection versus bipolar diathermy

Protocol summary

Summary

Study objective: evaluation of complication of tonsillectomy by Cold dissection versus bipolar diathermy(ligature). Design: randomized, not controlled by placebo, unicentered, phase 1 trial. Inclusion criteria: patients with recurrent or chronic tonsillitis; sleep apnea; presence of debris in tonsillar crypts; adenotonsillar hypertrophy with snoring. Exclusion criteria: severe asthma; coagulopathy; diabetes mellitus; sickle cell anemia; neurologic deficits; acute infection; simultaneous myringotomy or VT insertion; simultaneous lymph node biopsy; socially inaccessible(no telephone or car). Sample size:82. Intervention: bipolar diathermy(ligature) surgery. Intervention time: 22.6.2013-20.3.2015. Primary outcome: pain, bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102113976N2**
Registration date: **2013-12-17, 1392/09/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-17, 1392/09/26

Registrant information

Name

Javaneh Jahanshahi

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0020

Email address

j.jahanshahi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of complication of tonsillectomy by Cold dissection versus bipolar diathermy

Public title

Evaluation of complication of tonsillectomy by Cold dissection versus bipolar diathermy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with recurrent or chronic tonsillitis; sleep apnea; presence of debris in tonsillar crypts; adenotonsillar hypertrophy with snoring. Exclusion criteria: severe asthma; coagulopathy; diabetes mellitus; sickle cell anemia; neurologic deficits; acute infection; simultaneous myringotomy or VT insertion; simultaneous lymph node biopsy; socially inaccessible(no telephone or car).

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 82

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan university of medical sciences

Street address

Hamedan

City

Hamedan

Postal code

6514845411

Approval date

2013-04-09, 1392/01/20

Ethics committee reference number

16/35/9/44/د/پ

Health conditions studied

1

Description of health condition studied

Chronic tonsillitis

ICD-10 code

J35

ICD-10 code description

Chronic diseases of tonsils and adenoids

Primary outcomes

1

Description

pain

Timepoint

24 hours postoperation, 1 week, 2 weeks, 4 weeks postoperation

Method of measurement

visual analogue scale

2

Description

bleeding

Timepoint

24 hours postoperation , 1 week, 2 weeks, 4 weeks postoperation

Method of measurement

milliliter

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: bipolar diathermy(ligature): tonsils are removed by bipolar cautery scissors and hemostasis is established. Surgery time is documented from mouth gag insertion to its removal. Bleeding volume is documented, too by looking at the suction bottle.

Category

Treatment - Surgery

2

Description

control group: tonsillectomy is done by cold dissection method. Tonsil and its capsule is removed by tonsil decolor. The inferior pole is cut by snare and hemostasis is established by vicryl 20.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan University of Medical Sciences

Full name of responsible person

Javaneh Jahanshahi

Street address

Besat hospital, Shahid Motahari boulevard, Hamedan.

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

Street address

research and technology department, hamedan

university of medical sciences, shahid fahmideh
street

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences, Faculty of
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Full name of responsible person

Javaneh Jahanshahi

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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