

# 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  
Dentistry

**Full name of responsible person**

Javaneh Jahanshahi

**Position**

Assistant professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*