Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparision of complecation of of tonsillectomy in two methods of cold dissection and Bipolar with harmonic scalpel in patients with tonsillar hypertrophy and recurrent tonsillitis

Protocol summary

Summary

Tonsillectomy is a common surgery. Indications for tonsillectomy in adults are chronic or recurrent tonsil infections, airway obstruction due to hypertrophy of the tonsils and suspicion of malignancy. In our study, single blind clinical trial, 32 patients 48-14 years old who are candidate for tonsillectomy are selected in Amir Alam Hospital. All patients will undergo tonsillectomy by one surgeon with similar method. In each patient tonsillectomy will be done randomly for each side by the harmonic method or cool dissection. The pain on each side on the first and the seventh days will be recorded. Primary outcome: time of surgery; The volume of intraoperative bleeding Secondary outcomes: postoperative bleeding; postoperative pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609179039N4**
Registration date: **2017-02-09, 1395/11/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name
Shahin Bastaninezhad
Name of organization / entity
Dep. ENT, AmirAlam Hospital
Country
Iran (Islamic Republic of)
Phone
+98 21 6676 0269
Email address
shahinbastani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellorfor Research, School of Medicine,Tehran University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparision of complecation of of tonsillectomy in two methods of cold dissection and Bipolar with harmonic scalpel in patients with tonsillar hypertrophy and recurrent tonsillitis

Public title

The comparision of two methods of tonsillectomy convensional and harmonic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Tonsillar hypertrophy; recurrent tonsillitis Exclusion criteria: Histiry of coagulopathy or anticoagulant therapy; past tonsillectomy; speech disorder; mental and developmental disorders

Age

From **14 years** old to **48 years** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **32**
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
Ethics Committee of Tehran University of Medical Sciences
Street address
Ghods Street, Keshavarz Boulevard
City
Tehran
Postal code
1417653761
Approval date
2016-02-10, 1394/11/21
Ethics committee reference number
IR.TUMS.REC.1394.1938

Health conditions studied

1

Description of health condition studied
Chronic tonsillitis
ICD-10 code
J35.1
ICD-10 code description
J35.1 Hypertrophy of tonsils Enlargement of tonsils

Primary outcomes

1

Description
surgery time
Timepoint
from incision to end of hemostasis of the same side
Method of measurement
Cronometer

2

Description
The volume of intraoperative bleeding
Timepoint
from incision to end of hemostasis of the same side
Method of measurement
Measuring the suction bottle and weightening of bloody gazes

Secondary outcomes

1

Description
postoperative bleeding
Timepoint
after operation
Method of measurement
Bleeding or no bleeding after surgery

2

Description
postoperative pain
Timepoint
first and seventh days after surgery
Method of measurement
Pain scale scoring system

Intervention groups

1

Description
Harmonic group: Side of tonsillectomy with harmonic scalpel in 32 patients
Category
Treatment - Surgery

2

Description
Cold dissection group: side of tonsillectomy in fasion of cold dissection with bipolar in 32 patients
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralam hospital
Full name of responsible person
Dr Alireza Safaee
Street address
City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellorfor Research, School of Medicine,Tehran University of Medical Sciences

Full name of responsible person
Dr Shahin Akhondzadeh

Street address
Poursina street, Ghods Street, Enghelab street

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellorfor Research, School of Medicine,Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr Alireza Safaee

Position
Resident of ENT

Other areas of specialty/work

Street address
AmirAlam Hospital, Saadi Ave, Enghelab Street

City
Tehran

Postal code
1145765111

Phone
+98 21 6670 8103

Fax

Email
alireza_safaee@ymail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Shahin Bastaninejad

Position
Asistant professor of ENT

Other areas of specialty/work

Street address
AmirAlam Hospital, Saadi Ave, Enghelab Street

City
Tehran

Postal code
1145765111

Phone
+98 21 6670 3037

Fax
+98 21 6676 0269

Email
shahinbastani@razi.tums.ac.irdr_shahinbastani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Alireza Safaee

Position
Resident of ENT

Other areas of specialty/work

Street address
AmirAlam Hospital, Saadi Ave, Enghelab Street

City
Tehran

Postal code
1145765111

Phone
+98 21 6670 8103

Fax

Email

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