

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The results of radiofrequency tonsillectomy compared with conventional cold dissection tonsillectomy in recovery of adults with recurrent tonsillitis.

Protocol summary

Summary

We want to compare the results and complications of surgery between traditional tonsillectomy and tonsillectomy by radiofrequency in adults suffering from chronic or recurrent tonsillitis. 60 patients older than 15 years old, suffering from recurrent episodes of tonsillitis referred to the ENT service in Rasht, Amiralmomenin hospital are randomly separated into two groups. One group underwent traditional tonsillectomy and the other was treated by Radiofrequency (RF). Those with underlying bleeding disorders especially who had to use ASA or heparin were left out of the study. Operation in the two groups was done under general anesthesia. The manner how to perform the procedure and also the instruments used in the operating room, were similar in all patients. The tonsils were ablated near totally with especial probes. A wide comparison between the two groups was done according to the followings: The amount of bleeding during surgery; Duration of operation & anesthesia; Time of recovery; Pain-scale after surgery (especially in the 1st, 3rd, 5th & 10th days after surgery); Dysphagia; Date of rehabilitation; Date of taking routine diet; The patient's weight after surgery (especially in the 3rd -10th & 20th days after surgery); Complications such as post operation, bleeding, halitosis, snoring, frequency of tonsillitis & pharyngitis in the 6th & 12th & 15th months after operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010091138N3**
Registration date: **2011-06-07, 1390/03/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-07, 1390/03/17

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences, Vice chancellor for Research

Expected recruitment start date

2008-04-08, 1387/01/20

Expected recruitment end date

2010-01-10, 1388/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The results of radiofrequency tonsillectomy compared with conventional cold dissection tonsillectomy in recovery of adults with recurrent tonsillitis.

Public title

Effect of radiofrequency tonsillectomy in recurrent

tonsillitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: adult patients (aged 15-65 years) with recurrent tonsillitis was performed in a tertiary referral university hospital that candidated for surgery. Exclusion criteria: Those who had underlying bleeding disorders; who had to use ASA or heparin; those with immunologic disorders.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **62**

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

Ethic committee of Guilan University of Medical Sciences

Street address

Siadati st.

City

Rasht

Postal code

Approval date

2007-06-10, 1386/03/20

Ethics committee reference number

1683

Health conditions studied

1

Description of health condition studied

Chronic Tonsillitis

ICD-10 code

J35.9

ICD-10 code description

Chronic disease of tonsils and adenoids

Primary outcomes

1

Description

postsurgical pain

Timepoint

on days 1, 3, 5 and 10 after surgery

Method of measurement

Visual Analogue Scale (VAS)

2

Description

recurrence of tonsillitis/pharyngitis episodes

Timepoint

on months 6, 12 and 15 after surgery

Method of measurement

ask from patient and periodic check-up

Secondary outcomes

1

Description

weight

Timepoint

in the 3rd, 10th and 20th days after surgery

Method of measurement

scale

2

Description

intraoperative bleeding

Timepoint

During and end of surgery

Method of measurement

measuring the blood volume in the vacuum bottle and also by counting the surgical gauzes

Intervention groups

1

Description

Surgery will be done under general anesthesia and the operation in control group will be done by standard method of cold dissection tonsillectomy (i.e. dissecting the palatal tonsils from their bed by surgical knife and separating and totally removal of the tonsils from their sites). Duration of operation is measured according to the time, when surgical field is exposed (after accomplishing the anesthesia) till the moment that the surgeon is sure that there is no bleeding in the field of operation. At the end of the procedure, the amount of bleeding is estimated by measuring the blood volume in the vacuum bottle and also by counting the surgical

gauzes, used in the operating room during surgery. The pain scale after surgery is measured by Visual Analogue Scale from zero to ten centimeters in the 1st, 3rd, 5th and 10th days after surgery. The patients are asked about taking analgesia after surgery during the aforementioned days. The patients are also asked about the frequency of tonsillitis & pharyngitis during previous months, and at the same time the faucial tonsils are compared with their pre operation condition according to their size in the 6th, 12th and 15th months after surgery.

Category

Treatment - Surgery

2**Description**

With the patient under general anesthesia and in the Rose position, the oropharynx was exposed by use of a Davis gag, and bipolar-linear RFITT probe (Celon AG Medical Instruments, Teltow/Berlin, Germany) was introduced into the crypts of the tonsils. The RF generator working frequency was 470 kHz, which was set at 7 W during the procedure. The power was constantly controlled by the system, terminating the energy application automatically once the thermal lesion was created. Five points (i.e., tonsillar crypts, including crypts of inferior and superior poles) for grades 1 and 2 tonsils, seven points for grade 3, and nine points for grade 4 tonsils were probed.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmomenin Hospital

Full name of responsible person

Dr Shadman Nemati

Street address

17 shahrivar st.

City

Rasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Guilan University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Susan Komaii

Street address

Siadati st.

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Guilan University of Medical Sciences, Vice Chancellor for Research

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**

Guilan University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Position

Assistant professor

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

Amiralmomenin hospital, 17 shahrivar st.

City

Rasht

Postal code**Phone**

+98 13 1222 5242

Fax**Email**

nemati@gums.ac.ir

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

Guilan University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Position

Assistant professor

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

Amiralmomenin hospital, 17 shahrivar st.

City

Rasht

Postal code**Phone**

+98 13 1222 5242

Fax**Email**

nemati@gums.ac.ir

Web page address

Person responsible for updating data

Contact

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