

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effects of two methods of Cold Dissection and "Tonsillectomy Bipolar Resection" in patients aged 5 to 15 years undergoing tonsillectomy with or without adenoidectomy

Protocol summary

Study aim

Determination and comparison of the effects of two methods of Cold desiccation and "Tonsillectomy Bipolar Resection" in tonsillectomy

Design

This study was a clinical trial with two parallel and three-blind groups that were selected based on Sequential. The surgical procedure of the first specimen is selected by coin, then the procedure of the later specimens is selected according to the schedule

Settings and conduct

groups includes 38 patients that undergo tonsillectomy with or without adenoidectomy in the ENT of Khalili Hospital, Shiraz. The patient & his parents, researcher, are blinded. Patients follow up for a week & patients with postoperative bleeding who require surgical intervention under general anesthesia are identified and a questionnaire including the following information will be provided: age, gender, surgical indication, bleeding time, The location of bleeding, the cause of hemorrhage

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having consent to study, obtaining consent and full cooperation from parents of children, need for tonsillectomy, residing in Shiraz, children aged 5 to 15 years. Exclusion criteria: Lack of any preoperative infections, bleeding diseases, disorders in coagulation tests (PLT, P, PTT, INR), mental retardation, chronic underlying diseases (diabetes, cancer, etc.)

Intervention groups

In the first group, upper mucous membrane was given with a knife and then the blunt dissection was taken to separate the tonsil from the base, then the snare amputate the tonsil in the lower pole. In the second group, done by the Tonsillectomy Bipolar Resection method, the surgeon removes the special wire behind the tonsil, after fixing the wire, the coagulation button is

pushed to simultaneously cut & coagulate

Main outcome variables

User friendly method; Bleeding during and after surgery; Postoperative pain; duration of surgery; duration of return to activity & normal diet; surgical cost

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190106042251N1**

Registration date: **2019-08-17, 1398/05/26**

Registration timing: **retrospective**

Last update: **2019-08-17, 1398/05/26**

Update count: **0**

Registration date

2019-08-17, 1398/05/26

Registrant information

Name

jamshid eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4257

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jam_eslami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of two methods of Cold Dissection and "Tonsillectomy Bipolar Resection" in patients aged 5 to 15 years undergoing tonsillectomy with or without adenoidectomy

Public title

Efficiency of Tonsillectomy Bipolar Resection device in tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having satisfaction with the study Getting the consent and full cooperation of the parents of children The need for performing Tonsillectomy Staying in Shiraz Children in the age range of 5 to 15 years

Exclusion criteria:

Preoperative infection Having bleeding diseases Disturbances in coagulation tests (PLT, PT, PTT, INR) Having a mental retardation Chronic underlying diseases (diabetes, cancer, etc.)

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **76**

More than 1 sample in each individual

Number of samples in each individual: **38**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description

In this study, patients and their parents, researchers, clinical caregivers, and data analyzers are blind. Surgery is done by the ENT surgeon and the information is given to the researcher irrespective of the type of surgical procedure. Coding is also used to analyze data.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7193613119

Approval date

2019-06-23, 1398/04/02

Ethics committee reference number

IR.SUMS.REC.1398.584

Health conditions studied**1****Description of health condition studied**

Tonsillectomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

User-friendly device

Timepoint

Immediately after the intervention

Method of measurement

Davis & Venkatesh technology acceptance questionnaire

2**Description**

The amount of bleeding during and after surgery

Timepoint

During the intervention, 1, 3 and 7 days after the intervention

Method of measurement

Subtracting the weight of blood-stained gauzes from the weight of surgical gauzes

Secondary outcomes**1****Description**

Mortality

Timepoint

1, 3 and 7 days after the intervention

Method of measurement

Percentage of deaths in a month

Intervention groups

1

Description

Control group: In this group, tonsillectomy is common with cold dissection. Adenoidectomy was performed in patients using Curettes and then a pack of nasopharyngeal for homeostasis was performed. In tonsillectomy, a first sharper dissection was made and a mucosal incision was performed with a knife. At the end, the snare will be used to amputate the tonsil in the lower pole. Patch and suture are also used to control bleeding.

Category

Treatment - Surgery

2

Description

Intervention group: Patients treated with Tonsillectomy Bipolar Resection. As the surgeon draws the special wire behind the tonsils, then after the fixation of the wire, the coagulation button is pressed to simultaneously cut and coagulate.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili hospital

Full name of responsible person

Fatemeh Fakhrealizadeh

Street address

Namazi Square, Khalili hospital

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7185886479

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Jamshid Eslami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Surgical Technology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Fakhrealizadeh

Position

tutor

Latest degree

Master

Other areas of specialty/work

Surgical Technology

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Person responsible for updating data

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tutor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data, except the device's technical map, can be shared after being unidentifiable.

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

All scholars working in academic and scientific institutions

Under which criteria data/document could be used

Creating a Better Quality and Performance Device for Tonsillectomy Under the Inventor of this Device (Researcher)

From where data/document is obtainable

For more information, please call 00989017680793 or email Fakhrealizadeh@sums.ac.ir

What processes are involved for a request to access data/document

Setting up a contract for any change in the invention of the researcher

Comments