

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Outcome During and After Tonsillectomy Surgery in Two Methods: "cold dissection" and "ligasure"

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of outcomes during and after tonsillectomy in cold dissection and ligasure in all patients referring to Boali Hospital in Sari

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

Registration date

2020-04-17, 1399/01/29

Design

The clinical trial has a control group, with parallel group, single blind, randomized, and sample size of 60 individuals.

Registrant information

Name

Maliheh Shirzad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

This is a single-blind clinical trial in which patients do not know which surgery group they will be in. Patients are randomly divided into cold dissection and ligation groups. The duration of surgery will range from the time the gag mouth is inserted to the time it is completed. Bleeding during surgery will be recorded by a scaled suction. Twenty four hours after surgery, all patients will be carefully examined for bleeding in the tonsils and eardrums, sore throats, nausea, vomiting after surgery.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 2 years of age who are candidates for Tonsillectomy surgery; be satisfied with the operation; perform Tonsillectomy for the first time.

Non-inclusion criteria: Patients have a history of adenoidectomy; coagulation disorders and reoperation.

Expected recruitment start date

2020-03-12, 1398/12/22

Expected recruitment end date

2020-05-30, 1399/03/10

Intervention groups

Intervention group 1: Tonsillectomy by ligasure method.

Intervention group 2: Cold dissection tonsillectomy.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Bleeding during surgery; postoperative bleeding; sore throat; earache; nausea and vomiting; duration of surgery

Trial completion date

empty

General information

Scientific title

Comparison of the Outcome During and After Tonsillectomy Surgery in Two Methods: "cold dissection" and "ligasure"

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190816044539N1**

Registration date: **2020-04-17, 1399/01/29**

Public title

Comparing two methods "Ligasure" and "cold dissection" on the consequences of tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 2 years of age who are candidates for tonsillectomy surgery Being satisfied with the participation in the study Perform tonsillectomy for the first time

Exclusion criteria:

Those with adenoidectomy Patients with coagulation disorders Having re-surgery tonsillectomy

Age

From 2 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The data collection method in this study will be done continuously and consecutively and in person based on the data collection form. Select the type of intervention in two groups of ligatures, cold dissection, as random allocation using (Block Randomization) (A, B, C, D) which according to the block number of sample 30 will be selected randomly using the table of random numbers and The number of patients referring to it will be determined accordingly, so the desired number will be wrote on the envelopes and the type of intervention will be placed inside the envelope. The researcher looks at the patient's bedside and looks at the type of intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

For blindness, it is done as a single blind. In fact, patients do not know in which group they are, but they are already aware of both methods and enter the study with complete satisfaction, because they were unconscious and therefore they were unaware which surgery method had been used for them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Pasdaran street- Imam Square - Sari

City

sari

Province

Mazandaran

Postal code

4815836798

Approval date

2020-03-11, 1398/12/21

Ethics committee reference number

IR.MAZUMS.REC.1398.1451

Health conditions studied

1

Description of health condition studied

Outcome during and after tonsillectomy

ICD-10 code

J03

ICD-10 code description

Acute tonsillitis

Primary outcomes

1

Description

Ear pain

Timepoint

1, 7, 14 days after tonsillectomy

Method of measurement

Visual Analogue Scale

2

Description

Sore throat

Timepoint

1, 7, 14 days after tonsillectomy

Method of measurement

Visual Analogue Scale

3

Description

Bleeding

Timepoint

Intraoperative and 1, 7, 14 days after tonsillectomy

Method of measurement

Scaled suction and observation

Secondary outcomes

1

Description

nausea and vomiting

Timepoint

1, 7, 14 days after tonsillectomy

Method of measurement

check list

2

Description

Duration of operation

Timepoint

Immediately after tonsillectomy

Method of measurement

check list

Intervention groups

1

Description

Intervention group: Tonsillectomy is performed with Ligashur. Ligashur is a new hemostatic electrical surgical device that consists of a surgical electrical generator, a hand-held scissor mechanism with a fork.

Category

Treatment - Surgery

2

Description

Control group: In the control group, the tonsillectomy will be performed by cold dissection, in which the tonsils and capsules will be separated from the surrounding tissues by the decoller, cut off from the lower part, the tonsils will be removed, and the hemostasis will be performed with 0.3 Vicryl suture.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

BouAli hospital

Full name of responsible person

Maliheh Shirzad

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

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City

sari

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Maliheh Shirzad

Position

University student

Latest degree

Master

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Nasiri

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Maliheh Shirzad

Position

University student

Latest degree

Master

Other areas of specialty/work

Ear, Nose, and Throat

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available