Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Tonsillectomy Outcomes Using LigaSure Device-Assisted Technique Versus Conventional Method

Protocol summary

Study aim
Comparison of the efficacy, complications, and clinical outcomes of two techniques, LigaSure and cold dissection, in tonsillectomy surgery.

Design
The present study is a phase 3, single-blind, controlled clinical trial with two parallel groups . Thirty eligible individuals will be randomly assigned to each group using random blocks

Settings and conduct
Sixty eligible patients referred to the clinic of Baqiyatallah Hospital, will be randomly divided into two groups: cold dissection and LigaSure. Intervention group: Tonsillectomy surgery is performed using LigaSure. Control group: Tonsillectomy is performed using cold dissection. patients do not know which group they have been assigned to, but they were informed about both methods beforehand and entered the study with full consent. Since they are under anesthesia, they are unaware of how their surgery was performed. Additionally, the treatment outcome assessor and the data analyst will be blinded to the study hypothesis.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients older than 3 years and younger than 16 years who are candidates for tonsillectomy surgery; have provided consent for the procedure; undergoing tonsillectomy for the first time. Exclusion criteria: Patients who have a history of incomplete tonsil surgery, have coagulation disorders, or withdraw from continued cooperation during the study.

Intervention groups
Tonsillectomy surgery is performed using LigaSure. Control group: Tonsillectomy is performed using cold dissection. In this method, the tonsil and its capsule are separated from the surrounding tissues using a dissector, detached from the lower pole, and the tonsil is removed.

Main outcome variables
Pain intensity at the surgical site (pharynx) based on the Visual Analogue Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260530069575N1**
Registration date: **2026-06-02, 1405/03/12**
Registration timing: **prospective**

Last update: **2026-06-02, 1405/03/12**
Update count: **0**

Registration date
2026-06-02, 1405/03/12

Registrant information

Name
Ismail Alhabash

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4405 8754

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-23, 1405/05/01

Expected recruitment end date
2027-05-22, 1406/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of Tonsillectomy Outcomes Using LigaSure Device-Assisted Technique Versus Conventional Method

Public title
Comparison of Tonsillectomy Outcomes Using LigaSure Device-Assisted Technique Versus Conventional Method
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 3 years and younger than 16 years who candidates for tonsillectomy surgery have provided consent for the procedure Patients that undergoing tonsillectomy for the first time.
Exclusion criteria:
Patients who have a history of incomplete tonsil surgery have coagulation disorders withdraw from continued cooperation during the study
Age
From **3 years** old to **16 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be performed using the random blocking method (four-block blocks). The possible blocks are as follows: 1- AABB, 2- ABAB, 3- BABA, 4- BBAA, 5- BAAB, 6- ABBA. At this stage, numbers (1 to 6) will be randomly selected using a random number table, and this process will be repeated 15 times until the sample size is reached
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients do not know which group they have been assigned to, but they were informed about both methods beforehand and entered the study with full consent. Since they are under anesthesia, they are unaware of how their surgery was performed. Additionally, the outcome assessor and the data analyst are blinded to the study hypothesis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Commmittee of Baqiyatallah Hospital
Street address
Baqiyatallah university, south sheikh bahai st, molasdra st, vanak sq
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2026-03-18, 1404/12/27
Ethics committee reference number
IR.BMSU.BAQ.REC.1404.157

Health conditions studied

1

Description of health condition studied
Tonsillectomy
ICD-10 code
J35.1
ICD-10 code description
Hypertrophy of tonsils

Primary outcomes

1

Description
Pain intensity at the surgical site (pharynx) based on the Visual Analogue Scale (VAS)
Timepoint
24 hours, 3 and 7 days after surgery
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Bleeding during operation
Timepoint
During surgery
Method of measurement
The volume of blood loss is calculated by counting the bloody gauzes (each saturated gauze = 15 mL) and collecting the blood in a graduated suction during the procedure, and is recorded in milliliters.

Secondary outcomes

1

Description

operation Time

Timepoint

The time from the start of surgery (the first contact of the instrument with the tissue) until the completion of incision and bleeding control is recorded with a chronometer and reported in seconds or minutes.

Method of measurement

During operation

2

Description

Infection

Timepoint

24 hours, 3 and 7 days after surgery

Method of measurement

Occurrence of an inflammatory response or local or systemic infection in the surgical area, characterized by symptoms such as fever, purulent discharge, foul odor, or redness

3

Description

Secondary Bleeding

Timepoint

24 hours, 3 and 7 days after surgery

Method of measurement

Observation of obvious bleeding from the mouth or nose (spitting blood, hematemesis)

4

Description

Posterior pillar injury

Timepoint

7 days after surgery

Method of measurement

Direct visual inspection: After removing the tonsil, the surgeon carefully examines the tonsillar fossa and both the anterior and posterior pillars using a retractor or speculum

Intervention groups

1

Description

Intervention group: onsillectomy surgery is performed using LigaSure. LigaSure is a new electrosurgical hemostatic device consisting of an electrosurgical generator, a handpiece with a forceps-like scissor mechanism, along with a manual or foot switch.

Category

Treatment - Surgery

2

Description

Control group: Tonsillectomy is performed using cold dissection. In this method, the tonsil and its capsule are separated from the surrounding tissues using a dissector, detached from the lower pole, and the tonsil is removed. Hemostasis is achieved using 3/0 Vicryl suture.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Ismail Al-Habash

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Baqiyatallah university, south sheikh bahai st, molasdra st, vanak sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abbas Ali Imani Fooladi

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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

Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ismail Al- Habash
Position
ENT Resident
Latest degree
Medical doctor
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Other areas of specialty/work
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Street address
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to patient confidentiality and privacy considerations, we have not received permission from the ethics committee to share individual patient data
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available