Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

SURGERY DURATION, WOUND HEALING PROCESS AND COMPLICATIONS OF BIPOLAR ELECTROCAUTERY DISSECTION VERSUS COLD DISSECTION TONSILLECTOMY IN ADULTS.

Protocol summary

Study aim

We are determining and comparing the duration of surgery, the wound healing process, and the complications caused by tonsillectomy by Bipolar Electrocautery Dissection and Cold Dissection methods in adults.

Design

A parallel-group, double-blind clinical trial on 60 patients.

Settings and conduct

This study will be conducted on patients aged 18 years and above who are candidates for tonsillectomy referring to Imam Khomeini Hospital in Ilam. The research environment will be the operating room and ear, throat, and nose surgery department of Imam Khomeini hospital in Ilam. On the left side, the tonsil will be separated from its bed by a scalpel cut and will be removed with forceps, and the bleeding will be controlled by suturing. On the right side, an incision will be made by bipolar forceps, the tonsil will be separated with forceps, and the bleeding will be controlled by electrocoagulation. in the next patient, the left and right interventions will be changed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Need to perform tonsillectomy, age range above 18 years, have consented to conduct the study Exclusion criteria: Having an infection before the operation, bleeding diseases and any disorders in coagulation tests, mental retardation, underlying diseases (diabetes, malignancy, severe asthma, sickle cell anemia, etc.), failure to complete the forms, lack of cooperation after the operation

Intervention groups

The cold dissection method will be used to remove the left tonsil and the Bipolar Electrocautery method will be used to remove the right tonsil, and the opposite will be done in the next patient.

Main outcome variables

duration of surgery; amount of bleeding during surgery; severity of sore throat; severity of earache; the number of postoperative bleeding episodes; percentage of pseudomembrane formed; The percentage of absorbed pseudomembrane

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230107057071N1**
Registration date: **2023-01-16, 1401/10/26**
Registration timing: **prospective**

Last update: **2023-01-16, 1401/10/26**
Update count: **0**

Registration date

2023-01-16, 1401/10/26

Registrant information

Name

Meysam Jahanbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 755 4043

Email address

meysam.j17@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
SURGERY DURATION, WOUND HEALING PROCESS AND COMPLICATIONS OF BIPOLAR ELECTROCAUTERY DISSECTION VERSUS COLD DISSECTION TONSILLECTOMY IN ADULTS.

Public title
SURGERY DURATION, WOUND HEALING PROCESS AND COMPLICATIONS OF BIPOLAR ELECTROCAUTERY DISSECTION VERSUS COLD DISSECTION TONSILLECTOMY IN ADULTS.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Need to perform tonsillectomy Age range above 18 years Consent to study
Exclusion criteria:
Having a preoperative infection Bleeding diseases and any disorders in coagulation tests Mental retardation underlying diseases (diabetes, malignancy, severe asthma, sickle cell anemia, etc.) Failure to complete the forms Lack of cooperation after the operation
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
The right palatal tonsil will be considered as one sample and the left palatal tonsil will be considered as another sample.
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants will not know which of the left or right tonsils will be operated on by Bipolar Electrocautery or Cold dissection. Those responsible for data collection will not know which of the left or right tonsils was operated by bipolar electrocautery or cold dissection. The data analysts will not know which of the left or right tonsils was operated by bipolar electrocautery or cold dissection.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ilam University of Medical Sciences
Street address
Ilam University of Medical Sciences; Banganjab; Pazhuhesh Blvd
City
Ilam
Province
Ilam
Postal code
6939177143
Approval date
2022-12-19, 1401/09/28
Ethics committee reference number
IR.MEDILAM.REC.1401.180

Health conditions studied

1

Description of health condition studied
Tonsillectomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of bleeding during surgery
Timepoint
After the end of the surgical procedure
Method of measurement
By measuring the amount of suctioned blood in the graduated suction minus the suctioned serum

2

Description
Duration of surgery
Timepoint
After the end of the surgical procedure
Method of measurement
The duration of the surgery from the moment of cutting to the moment of complete control of bleeding will be

recorded by a timer.

Secondary outcomes

1

Description
The severity of sore throat
Timepoint
24 hours, day 8, day 15, and day 22 after tonsillectomy
Method of measurement
Using the Visual Analogue Scale

2

Description
The severity of earache
Timepoint
24 hours, day 8, day 15, and day 22 after tonsillectomy
Method of measurement
Using the Visual Analogue Scale

3

Description
Number of bleeding episodes after surgery
Timepoint
Within 22 days after surgery
Method of measurement
Based on the patient's complaint within 22 days after surgery and also examination by the doctor at 24 hours, 8 days, 15 days, and 22 days after tonsillectomy.

4

Description
The percentage of pseudomembrane formed
Timepoint
24 hours, day 8, day 15, and day 22 after tonsillectomy
Method of measurement
Macroscopically by the doctor's examination

5

Description
The percentage of absorbed pseudomembrane
Timepoint
24 hours, day 8, day 15, and day 22 after tonsillectomy
Method of measurement
Macroscopically by the doctor's examination

Intervention groups

1

Description
Intervention group: Bipolar Electrocautery method will be used to remove the palatal tonsil on one side (for example, the right palatine tonsil). In this method, the incision will be made by bipolar forceps and the tonsil will be separated with forceps. Then the bleeding will be controlled by electrocoagulation.
Category
Treatment - Surgery

2

Description
Control group: To remove the palatine tonsil on the other side (for example, the left side), the Cold Dissection method will be used. In this method, the tonsil will be separated from its bed by a scalpel cut and removed with forceps. Then the bleeding will be controlled by suturing.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Meysam Jahanbakhsh
Street address
Ayatollah Heydari St
City
Ilam
Province
Ilam
Postal code
6931975397
Phone
+98 84 3333 4500
Email
emamkhominihospital@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Abbas Maleki
Street address
Ilam University of Medical Sciences; Banganjab; Pazhuhesh Blvd
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Province
Ilam
Postal code
6939177143
Phone
+98 84 3223 5724
Email
maleki-a@medilam.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Ilam 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
Ilam University of Medical Sciences
Full name of responsible person
Meysam Jahanbakhsh
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
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Person responsible for scientific inquiries

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Student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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Meysam Jahanbakhsh
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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Street address
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City
Ilam
Province
Ilam
Postal code
6939177143
Phone
+98 914 755 4043
Email
meysam.j17@gmail.com

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
There is no further information.
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
No - There is not 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
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the data, such as information related to the main outcome or similar, can be shared.
When the data will become available and for how long
The access period starts 6 months after the results are published.
To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Using the results of this study to compare with other studies is allowed.

From where data/document is obtainable

Applicants can contact us through the email address Meysam.j17@gmail.com.

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

After applying through the email address, the documents will be provided to the applicant within 48 hours.

Comments