

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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

emamkhomeinihospital@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

##### City

Ilam

##### 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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**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

meysam.j17@gmail.com

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

Ilam University of Medical Sciences

**Full name of responsible person**

Meysam Jahanbakhsh

**Position**

Student

**Latest degree**

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**Person responsible for updating data****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

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**Email**

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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**

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**