Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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

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

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.

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.

Intervention groups
Intervention group 1: Tonsillectomy by ligasure method.
Intervention group 2: Cold dissection tonsillectomy.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190816044539N1**
Registration date: **2020-04-17, 1399/01/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-17, 1399/01/29**
Update count: **0**

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

Registrant information
Name
Maliheh Shirzad
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-12, 1398/12/22

Expected recruitment end date
2020-05-30, 1399/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

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 therefor 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
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Pasdaran street- Imam Square - Sari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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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

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Associate Professor

Latest degree

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Other areas of specialty/work

Traditional Medicine

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Position

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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