Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The impact of application of amniotic membrane on post-tonsillectomy pain and bleeding

Protocol summary

Study aim

Aim of this study was the comparison of application of an amniotic membrane in tonsillectomy in adults regarding primary outcomes (pain and bleeding).

Design

In this randomized, single blind clinical trial, 60 patients who were candidate for tonsillectomy and eligible for inclusion in the study were selected. Participants were randomly divided into two groups; intervention and control.

Settings and conduct

Since the adoption of the proposal, patients who were candidates for tonsillectomy, were randomly divided into two groups of intervention and control.The randomization method was block randomization. The procedure of surgery were the same in the two groups. surgeries were conducted in Shahid Dastgheib Hospital. All the surgeries were performed by the performer. Outcome of pain was recorded by patient within 7 days after surgery, bleeding (within 14 days after operation) and percentage of wound healing (5, 10 and 15 days after surgery) were assessed by ENT specialist .The assistant co-worker then collected the information and delivered it to the statistician. The outcomes evaluator (physician) and statistician did not know about the procedure.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with 18 years of age or older; Patients undergoing tonsillectomy for indications of recurrent tonsillitis or tonsillar hypertrophy. Exclusion criteria: Patients who had previous peritonsillar abscess, acute infection, coagulatory problems, major organ disease like congestive heart failure, renal failure, hepatic failure or any other internal problems effecting the hemostasis condition.

Intervention groups

In intervention group, the aminiotic membrane used for coverage of muscle flap. In control group, the aminiotic membrane did not used for coverage of muscle flap.

Main outcome variables

Pain, bleeding and percentage of wound healing after tonsillectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131123015496N21**
Registration date: **2019-06-08, 1398/03/18**
Registration timing: **retrospective**

Last update: **2019-06-08, 1398/03/18**
Update count: **0**

Registration date

2019-06-08, 1398/03/18

Registrant information

Name
Sareh Roosta
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Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-03-18, 1397/12/27

Actual recruitment start date

2018-12-21, 1397/09/30

Actual recruitment end date

2019-03-18, 1397/12/27

Trial completion date

2019-03-18, 1397/12/27

Scientific title

The impact of application of amniotic membrane on post-tonsillectomy pain and bleeding

Public title

The impact of application of embryonic membrane in surgery to remove tonsils

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with 18 years of age or older Patients undergoing tonsillectomy for indications of recurrent tonsillitis or tonsillar hypertrophy.

Exclusion criteria:

Patients who had previous peritonsillar abscess, acute infection, coagulatory problems, major organ disease like congestive heart failure, renal failure, hepatic failure or any other internal problems effecting the hemostasis condition

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with one person and random numbers 0 to 9.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzer and those who evaluate the outcome (physicians) were unaware of the type of material used in practice.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiaz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

71345-1978

Approval date

2018-11-23, 1397/09/02

Ethics committee reference number

IR.SUMS.MED.REC.1397.353

Health conditions studied

1

Description of health condition studied

Tonsillectomy

ICD-10 code

J35.1, J35

ICD-10 code description

Hypertrophy of tonsils, Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description

Pain score intensity after tonsillectomy

Timepoint

Three times a day; before breakfast, lunch, dinner for 7 days after surgery

Method of measurement

Visual Analog Scale (VAS)-by patient

2

Description

Post-tonsillectomy bleeding

Timepoint

within 14 days after surgery

Method of measurement

Observation by ENT specialist

Secondary outcomes

1

Description

Percentage of wound healing

Timepoint

5, 10 and 15 days after surgery

Method of measurement

Observation by ENT specialist

Intervention groups

1

Description

Intervention group: The aminiotic membrane used for coverage of muscle flap in intervention group.

Category

Treatment - Surgery

2

Description

Control group: The aminiotic membrane did not used for coverage of muscle flap in control group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dastgheib Hospital

Full name of responsible person

Dr. Mohammad Faramarzi

Street address

Hafez Street, Next to National Garden

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71456-83769

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ghasemi

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Vice Chancellor for Research ,Shiraz University of Medical Sciences-7th floor-Central Building of Shiraz University of Medical Sciences , Zand Street

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sareh Roosta

Position

Statistical consultant

Latest degree

Master

Other areas of specialty/work

Biostatistics

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Person responsible for scientific inquiries

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Full name of responsible person

Mohammad Faramarzi

Position

Associate professor of Otolaryngology

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Sareh Roosta

Position
Statistical Consultant

Latest degree
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Other areas of specialty/work
Biostatistics

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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 more information.

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