

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study the effect of haemostatic absorbable powder in tonsillectomy compare with using sutur in tonsillectomy

Protocol summary

Summary

150 patients candidate for tonsillectomy without underlying disease are matched based on age , gender. They will be allocated into groups of case and control. Study is single blinded and patients will not be aware of the intervention group. For the control group no hemorrhage controlling powder will be used, and for the intervention group chitohem powder will be used to control the bleeding. Scale of pain and bleeding, time of starting oral feeding, required amount of analgesic medication and time of formation of fibrin layer after surgery is compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608174374N2**
Registration date: **2017-04-24, 1396/02/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-24, 1396/02/04

Registrant information

Name

Seiedreza Seiedmohammaddoulabi

Name of organization / entity

shahid beheshti university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 3333 9755

Email address

s8371916@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hearing research centre of Loghman Hakim hospital ,
Shahid Beheshti University Of Medical Sciences

Expected recruitment start date

2016-10-20, 1395/07/29

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of haemostatic absorbable powder in tonsillectomy compare with using sutur in tonsillectomy

Public title

Study the effect of haemostatic absorbable powder in tonsillectomy surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients candidate for tonsillectomy with age in range of 6-53 years old. exclusion criteria: blood disorders; bleeding tendency

Age

From **6 years** old to **53 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University Of
Medical Sciences

Street address

Daneshgah Square, Shahid Chamran Highway

City

Tehran

Postal code

11799-43613

Approval date

2016-05-08, 1395/02/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.148

Health conditions studied

1

Description of health condition studied

Hypertrophy of tonsils

ICD-10 code

J35.1

ICD-10 code description

Hypertrophy of tonsils

Primary outcomes

1

Description

presence or absence of bleeding

Timepoint

6,12,24 hours after surgery

Method of measurement

observation

2

Description

presence of fibrin membrane

Timepoint

6

Method of measurement

observation

3

Description

pain visual analogue scale

Timepoint

6"12"24 hours after surgery

Method of measurement

pain visual analogue scale

Secondary outcomes

1

Description

bleeding after surgery

Timepoint

24 hours after surgery

Method of measurement

observation

Intervention groups

1

Description

In case group we will use chitochem powder for control
hemorrhagea after tonsillectomy.

Category

Treatment - Surgery

2

Description

In control group use suture in site of surgery for control
hemorrhagea.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Navid Ahmadi roozbahani

Street address

Kamali street, Karegar street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Reza Seyed Mohammad Doulabi

Street address

Loghman Hakim Hospital, Kamali street, Karegar street

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Shahid Beheshti University Of Medical Sciences

Full name of responsible person

SeiedReza SeiedMohammadDoulabi

Position

Resident of otolaryngology

Other areas of specialty/work**Street address**

Loghman Hakim Hospital , Kamali street ,Karegar street

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

Loghman Hakim Hospital

Full name of responsible person

Navid Ahmadi Roozbahani

Position

Specialized Ear,Nasal,Trachea

Other areas of specialty/work**Street address**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Loghman Hakim Hospital

Full name of responsible person

Fahime Shamsian

Position

Medical Student

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty