# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

# Comparison of prevalence of post adenotonsillectomy hemorrhage requiring surgical intervention in hot dissection with cold dissection technique in children 3-10 years old admitted to Khatam-Ol-Anbia hospital of Zahedan during years 2016-18

## Protocol summary


**Summary**

The purpose of this study was to compare the frequency of bleeding requiring surgical intervention after adenotonsillectomy in two methods of hot dissection and cold dissection in 3-10 years old children. This study is a randomized, single-blind clinical trial that will be conducted in the ear, throat and nose ward of Khatam-Ol-Anbia Hospital of Zahedan. The study population included all 3-10 years old children who referred to the ENT clinic during the years of 2016-18 and are candidates for adenotonsillectomy. The inclusion criteria for entering the study include the absence of history of craniofacial surgery and other craniofacial diseases and craniofacial anomalies and the absence of coagulation disorders and immunodeficiency syndromes. Exclusion criteria include the use of anti-coagulant drugs and the lack of parental cooperation. The sample size is 60 person in each group. Patients are randomly divided into two groups, all patients undergo general anesthesia with the same protocol and adenotonsillectomy will be performed by one person in both groups. Adenotonsillectomy is performed in one of the groups by hot dissection and in other group by cold dissection method. After surgery, all patients will receive a same type of analgesic. Patients are then checked for variables such as the incidence of bleeding during the first 24 hours of the postoperative period or after 24 hours and the pain score 12 hours after the operation and one week after the operation and are registered in pre-prepared checklists.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017050633838N1**

Registration date: **2017-11-01, 1396/08/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

**Registration date**

2017-11-01, 1396/08/10

**Registrant information**

**Name**

Esmaeil Rahmanian

**Name of organization / entity**

Zahedan university of medical sciences

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

esmaeil.rahmanian@zaums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research of Zahedan University of Medical Sciences

**Expected recruitment start date**

2016-09-22, 1395/07/01

**Expected recruitment end date**

2018-09-23, 1397/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of prevalence of post adenotonsillectomy hemorrhage requiring surgical intervention in hot dissection with cold dissection technique in children 3-10 years old admitted to Khatam-Ol-Anbia hospital of Zahedan during years 2016-18

**Public title**
Comparison of prevalence of post adenotonsillectomy hemorrhage requiring surgical intervention in hot dissection with cold dissection technique
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Major inclusion factors include absence of history of maxillofacial surgery؛ absence of history of other diseases of the ear, throat and nose and craniofacial anomalies؛ lack of history of underlying and systemic diseases؛ absence of hematologic diseases such as sickle cell anemia؛ absence of coagulation disorders؛ absence of immunodeficiency or immunodeficiency syndromes. Major exclusion factors include use of anti-coagulant drugs؛ the lack of parental cooperation.
**Age**
From **3 years** old to **10 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **120**
**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 Zahedan university of medical sciences
**Street address**
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan
**City**
Zahedan
**Postal code**
**Approval date**
2017-03-07, 1395/12/17
**Ethics committee reference number**
IR.ZAUMS.REC.1395. 102

## Health conditions studied

### 1

**Description of health condition studied**
Acute tonsillitis, unspecified
**ICD-10 code**
J03.9
**ICD-10 code description**
Tonsillitis (acute): NOS follicular gangrenous infective ulcerative

## Primary outcomes

### 1

**Description**
Hemorrhage
**Timepoint**
During one week after operation
**Method of measurement**
Physical examination

## Secondary outcomes

### 1

**Description**
Pain
**Timepoint**
12 hours and one week after operation
**Method of measurement**
Numeric and visual scale of pain

## Intervention groups

### 1

**Description**
Adenotonsillectomy by cold dissection technique which tonsils are dissected by sharp tools without use of electrocauter.
**Category**
Treatment - Surgery

### 2

**Description**
Adenotonsillectomy by hot dissection technique which tonsils are dissected by electrocautery.
**Category**
Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Khatam-Ol-Anbia Hospital

**Full name of responsible person**
Khatam-Ol-Anbia Hospital, Jam e Jam Avenue, Zahedan

**Street address**
Dr Reza Ghariby

**City**
Zahedan

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice chancellor for research of Zahedan University of Medical Sciences

**Full name of responsible person**
Dr Hushang Rafighdust

**Street address**
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

**City**
Zahedan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Vice chancellor for research of Zahedan 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**
Zahedan University of Medical Sciences

**Full name of responsible person**
Dr Reza Ghariby

**Position**
Assistant Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Otolarangologist

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## Person responsible for updating data

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## 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*