

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Post-Tonsillectomy Pain using Succinylcholine versus Cisatracurium

#### Protocol summary

##### Study aim

To compare the post-tonsillectomy pain using Succinylcholine versus Cisatracurium in children and adolescents under 18 years old

##### Design

In this randomized, double blind clinical trial, 84 patients who were candidate for a tonsillectomy and eligible for inclusion in the study were selected. Participants were randomly divided into 2 medicine intervention groups.

##### Settings and conduct

Since the adoption of the proposal, patients who were candidates for a tonsillectomy, were randomly divided into two groups of Succinylcholine and Cisatracurium. The randomization method was Block Randomization. The procedure and anesthesia were the same in the two groups. surgeries were conducted in educational hospitals under supervision of Shiraz University of Medical Sciences. All the surgeries were performed by the performer. Outcome of pain were recorded by patients or their parents within 7 days after surgery. The assistant co-worker then collected the information and delivered it to the statistician. The statistician did not know about the procedure.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 3 - 18 years old children and adolescents; no physical or psychological problems; living nearby the hospital; at least one of the parents should have high school education. Exclusion criteria: congenital syndromes; immunodeficiency; any systemic or psychiatric diseases; family history of pseudocholinesterase deficiency

##### Intervention groups

One group received Succinylcholine 1.5 mg/kg and the other one Cisatracurium 0.15 mg/kg, as muscle relaxant in tonsillectomy.

##### Main outcome variables

post-tonsillectomy pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131123015496N20**

Registration date: **2018-06-15, 1397/03/25**

Registration timing: **retrospective**

Last update: **2018-06-15, 1397/03/25**

Update count: **0**

##### Registration date

2018-06-15, 1397/03/25

##### Registrant information

##### Name

Sareh Roosta

##### Name of organization / entity

Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3612 5323

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2014-06-21, 1393/03/31

##### Expected recruitment end date

2014-08-20, 1393/05/29

##### Actual recruitment start date

2014-06-21, 1393/03/31

##### Actual recruitment end date

2014-08-20, 1393/05/29

##### Trial completion date

empty

## Scientific title

Comparison of Post-Tonsillectomy Pain using Succinylcholine versus Cisatracurium

## Public title

Comparison of Post-Tonsillectomy Pain using Succinylcholine versus Cisatracurium

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

3 - 18 years old children and adolescents; no physical or psychological problems; living nearby the hospital; at least one of the parents should have high school education.

### Exclusion criteria:

immunodeficiency, congenital syndromes; any systemic or psychiatric diseases; family history of pseudocholinesterase deficiency

## Age

From **3 years** old to **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **88**

Actual sample size reached: **84**

## Randomization (investigator's opinion)

Randomized

## Randomization description

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

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants, data analyzer and those who evaluate the outcome, that is, the participants or their parents 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

2013-09-25, 1392/07/03

## Ethics committee reference number

CT-P-92-5085

## 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

1, 2, 4 Hours after tonsillectomy and then four times a day; before breakfast, lunch, dinner and also before sleep for 7 days after surgery

#### Method of measurement

Faces Pain Scale (FPS-R)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: received Succinylcholine (S.choline) 1.5 mg/kg t Cisatracurium 0.15 mg/kg, as muscle relaxant in operation room.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: received Cisatracurium 0.15 mg/kg, as muscle relaxant in operation room.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Dastgheib Hospital

**Full name of responsible person**

Dr. Mohammad Faramarzi

**Street address**

Next to National Garden, Hafez Street

**City**

Shiraz

**Province**

Fars

**Postal code**

71456-83769

**Phone**

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**Email**

dhospital@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Seyed Basir Hashemi

**Street address**

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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vcrdep@sums.ac.ir

**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

#### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Faramarzi

**Position**

Associate Professor of Otolaryngology

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Department of Otolaryngology, Khalili Hospital, Khalili Street

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

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**Position**

Statistical Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Biostatistics

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**Province**

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**Postal code**

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**Phone**

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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 are no more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable