

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)

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namazi_balini@sums.ac.ir

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi

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Vice Chancellor for Research ,Shiraz University of
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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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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

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Person responsible for updating data

Contact

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Shiraz University of Medical Sciences

Full name of responsible person

Sareh Roosta

Position

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Latest degree

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Other areas of specialty/work

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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