

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The efficacy of Ropivacaine Local Injection on Postoperative Pain in Patients with tonsillectomy surgery

Protocol summary

Study aim

The efficacy of Ropivacaine Local Injection on Postoperative Pain in Patients with tonsillectomy surgery

Design

Double-Blinded Randomized Clinical Trial

Settings and conduct

99 patients who were compared in three groups of 33 in Shahid Dastgheib, Dena and Khalili hospitals. Patients in the intervention group All patients aged 5 to 12 years with chronic tonsillitis with obstructive symptoms without response to medical treatment are candidates for adenotonsillectomy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with chronic tonsillitis with obstructive symptoms without responding to medical treatment are candidates for adenotonsillectomy. Patients who are candidates for elective tonsillectomy. Age 5 to 12 years, Patients who are candidates for elective tonsillectomy; consent to participate in this research project. exclusion criteria: coagulation disorders; history of ropivacaine allergy; People with underlying diseases such as asthma; weight less than 15 kg; children with heart, kidney, or liver disease; non-cooperating parents; non-cooperating patients (cerebral palsy, ...)

Intervention groups

Intervention group 1: In this group, 33 patients will inject 3 mg/kg of 1% ropivacaine made by Molteni (equivalent to 5 ccs) 5 minutes before tonsillectomy and 5 ccs of Distilled water 5 minutes after tonsillectomy.
Intervention group 2: In this group, 33 patients will be injected with 5 ccs of distilled water for 5 minutes before tonsillectomy and 5 ccs of 1% ropivacaine solution (manufactured by Multeni) and after tonsillectomy.
Group 3 or control group: In this group, 33 patients will be injected with 5 ccs of distilled water for 5 minutes before tonsillectomy and 5 ccs of distilled water after tonsillectomy

Main outcome variables

painless after tonsillectomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190511043550N3**

Registration date: **2022-01-12, 1400/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-12, 1400/10/22**

Update count: **0**

Registration date

2022-01-12, 1400/10/22

Registrant information

Name

Ashkan Panah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

panah@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-26, 1400/10/05

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The efficacy of Ropivacaine Local Injection on Postoperative Pain in Patients with tonsillectomy surgery

Public title
The efficacy of Ropivacaine Local Injection on Postoperative Pain in Patients with tonsillectomy surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for elective tonsillectomy All patients with chronic tonsillitis with obstructive symptoms without responding to medical treatment who are candidates for adenotonsillectomy Age 5 to 12 years Satisfaction with participating in a research project
Exclusion criteria:
History of Coagulation disorders History of Ropivacaine allergy Weight less than 15 kg Children with heart disease Children with kidney disease Children with liver disease Children with respiratory disease Children with mental disabilities

Age
From **5 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the block randomization method. Samples (99 patients) by random block method with 9 blocks (including 33 participants in intervention group 1 and 33 participants in intervention group 2 and 33 participants in the control group) with The use of a table of random numbers extracted from the relevant software will be specified. The blocks are equal and blocking and the ability to assign a random number for concealment by a non-involved person in the research will be done by recording the numbers on non-transparent envelopes, then based on the obtained blocks and the sequence of drug allocation in the operating room This is a double-blind study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Topical injection of ropivacaine solution or placebo is done by grouping and all cases by a surgeon who is blind to the study to minimize errors in the procedure. Randomization will be performed by a nurse who has no role in data collection.

Placebo
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, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2021-10-11, 1400/07/19

Ethics committee reference number

IR.SUMS.MED.REC.1400.413

Health conditions studied

1

Description of health condition studied

Tonsillectomy

ICD-10 code

J35.01

ICD-10 code description

Chronic tonsillitis

Primary outcomes

1

Description

Postoperative pain

Timepoint

From the moment of entering the recovery, 1, 4, 8, 16, 24 hours after entering the recovery room.

Method of measurement

Postoperative pain is measured using the Faces Pain Rating Scale at intervals of 1, 4, 8, 16, 24 hours after entering the recovery room by a trained nurse who is unaware of the injectable drug. After the patient is discharged, the trained nurse teaches one of the patient's first-class members in the recovery room and ward in the first few hours how to measure the pain, and records it with their help, and completes the rest at home and by phone at The relevant file is inserted.

Secondary outcomes

1

Description

The effect of ropivacaine injection before and after tonsillectomy on the need for acetaminophen suppositories.

Timepoint

From the moment of entering the recovery, 1, 4, 8, 16, 24 hours after entering the recovery room.

Method of measurement

Faces pain Rating scale

Intervention groups

1

Description

Intervention group 1: In this group, 33 patients will inject 3 mg/kg of 1% ropivacaine made by Molteni (equivalent to 5 ccs) 5 minutes before tonsillectomy and 5 ccs of Distilled water 5 minutes after tonsillectomy.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, 33 patients will be injected with 5 ccs of distilled water for 5 minutes before tonsillectomy and 5 ccs of 1% ropivacaine solution (manufactured by Multeni) after tonsillectomy.

Category

Treatment - Drugs

3

Description

Group 3 or control group: In this group, 33 patients will be injected with 5 ccs of distilled water for 5 minutes before tonsillectomy and 5 ccs of distilled water after tonsillectomy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospita

Full name of responsible person

Zahra Aria

Street address

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2

Recruitment center

Name of recruitment center

Shahid Dastgheib Hospital

Full name of responsible person

Zahra Aria

Street address

Hafez Street

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3

Recruitment center

Name of recruitment center

Dena Hospital

Full name of responsible person

Zahra Aria

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Bolvar-e-Sattar Khan, No. Sattar Khan cross toward north

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64951-71867

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info@denahospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

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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

peyman

Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Ashkan panah

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Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable