Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Glossopharyngeal nerve block compared to Ropivacaine infiltration as part of a multimodal analgesic regimen for post tonsillectomy pain relief in children A randomized controlled clinical study

Protocol summary

Study aim

Glossopharyngeal nerve block compared to Ropivacaine infiltration as part of a multimodal analgesic regimen for post tonsillectomy pain relief in children A randomized controlled clinical study

Design

In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 90 patients who will be undergoing tonsillectomy surgery will be enrolled. Eligible patients will be randomly allocated into two equal R, G and C groups by block randomization.

Settings and conduct

Patients who are candidates for tonsillectomy surgery who visit Dena Hospital in Shiraz during the study will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups using the random block method. This study will be conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with ASA grade I or II, patients between 4 and 10 years old, Candidate for tonsillectomy surgery and The distance between the hospital and the patient's place of residence should be a maximum of 30 minutes by car. Exclusion criteria: Allergy to the drugs used in the study Positive history of liver, kidney, and Obstructive sleep apnoea.

Intervention groups

Intervention group G: In all three groups, patients receive the analgesic regimen of ketamine and dexamethasone. The surgeon injects 5 ml of Ropivacaine solution on each side of the glossopharyngeal block. Intervention group R: The surgeon performs the injection using 5 ml of Ropivacaine solution on each side of the tonsil cavity. Control group C: patients receive Paracetamol and ketorolac in addition to the pain reliever regimen, and in order to blind the study, at the end of the operation, an equal number of injections are performed, similar to groups G and R, using a placebo (normal saline).

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003213N11**
Registration date: **2024-01-28, 1402/11/08**
Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**
Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Arash Farbood

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-01, 1402/12/11

Expected recruitment end date

2024-12-01, 1403/09/11

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Glossopharyngeal nerve block compared to Ropivacaine infiltration as part of a multimodal analgesic regimen for post tonsillectomy pain relief in children A randomized controlled clinical study

Public title
Glossopharyngeal nerve block compared to Ropivacaine infiltration in improving tonsillectomy pain in children.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ASA grade I or II (American Society of Anesthesiology classification) Patients between 4 and 10 years old Candidate for tonsillectomy or adenotonsillectomy with diagnosis of tonsillitis The distance between the hospital and the patient's place of residence should be a maximum of 30 minutes by car
Exclusion criteria:
Allergy to the drugs used in the study Positive history of liver, kidney, Coagulation disorders and Diseases of the digestive system Positive history of uncontrolled diseases of the cardiovascular system Obstructive sleep apnoea Taking painkillers other than study drugs in 24 hours before surgery
Age
From **4 years** old to **10 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly allocated into three groups by block randomization. In this technique, a permutation block of size 6 will be made for patients of two groups G,R & C. In each block, equal numbers for three groups will be considered in alternative positions. Then 15 blocks of size 6 will be selected randomly and patients will be allocated randomly and equally into three groups according to these permutation block. block sequence will be prepare by www.sealedenvelope.com.
Blinding (investigator's opinion)
Double blinded
Blinding description
In group G, the surgeon will inject 5 ml of 0.2% ropivacaine solution in the glossopharyngeal block. In group R, the surgeon will inject 5 ml of 0.2% ropivacaine solution in the tonsil cavity and its surrounding areas. In group C, at the end of the operation, in order to blind the study in half of the group (15 people), similar to the intervention group (G), the glossopharyngeal nerve block was performed by the surgeon using a placebo (0.9% normal saline) and in 15 people Another group, similar to group (R), is infiltration in the tonsil cavity with a placebo (0.9% normal saline solution). In the operating room, all study drugs will be provided by the only person familiar with the study (Nurse anesthetist). The anesthesiologist, patients, and other personnel involved in the work are blinded to the drugs injected in this study. This study is double-blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz Medical School
Street address
3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.
City
Shiraz
Province
Fars
Postal code
7134844119
Approval date
2023-11-27, 1402/09/06
Ethics committee reference number
IR.SUMS.MED.REC.1402.388

Health conditions studied

1

Description of health condition studied
Tonsillectomy
ICD-10 code
J03.9
ICD-10 code description
Acute tonsillitis, unspecified

Primary outcomes

1

Description

Pain

Timepoint

Every 15 minutes in the recovery room and at 24, 12, 6, 4, 2 hours after surgery

Method of measurement

CHEOPS scale

Secondary outcomes

1

Description

The quality of the patient's sleep

Timepoint

First time

Method of measurement

In respect to standardized questionnaire

2

Description

Painless swallowing

Timepoint

First time

Method of measurement

Patient history taking

3

Description

The level of satisfaction of the patient's parents

Timepoint

After recovery

Method of measurement

In respect to standardized questionnaire

Intervention groups

1

Description

Intervention group (G) : In all three groups, after the induction of anesthesia, the patients receive intravenous drugs of the studied analgesic regimen, which includes 500 µg/kg of ketamine and 150 µg/kg of dexamethasone. All surgeries will be performed by an otolaryngologist and cold dissection with ligature method. At the end of the surgery, in group (G), the surgeon injects 5 ml of 0.2% ropivacaine solution on each side of the glossopharyngeal nerve block. (Using a size 25 spinal needle at a 45 degree angle, it is inserted into the middle part of the palatopharyngeal fold in the back mucosa tissue of the pharynx, and then with a depth of 0.5 cm in the back wall of the pharynx, after negative aspiration, the injection is performed).

Category

Treatment - Drugs

2

Description

Intervention group (R) : At the end of surgery, in group (R), The surgeon w injects 5 ml of 0.2% Ropivacaine solution in the tonsil cavity and its surrounding areas after negative aspiration.

Category

Treatment - Drugs

3

Description

Control group (C) : After the induction of anesthesia, in addition to receiving intravenous drugs for the studied analgesic regimen, which is common in all groups, the basic analgesic regimen includes Paracetamol at the rate of 15 mg/kg and ketorolac at the rate of 470 µg/kg. receive intravenously and in order to blind the study, In group C, at the end of the operation, 15 people, similar to the intervention group (G), and another 15 people, similar to the intervention group (R), were injected using a placebo (0.9% normal saline).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dena Hospital

Full name of responsible person

Maryam Nemati

Street address

Dena Hospital, Blvd-E-Sattar Khan, Zargari Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Maryam Nemati

Position
Anesthesiology resident/physician

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Hamide Saeedizade

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Research Assisstant

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Bachelor

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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
It is against our policy.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary	No - There is not a plan to make this available