Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Topical Ropivacaine Spray on Relief of Post-Tonsillectomy Pain in Children

Protocol summary

Study aim

1- Evaluation and comparison of severity of postoperative pain in case (ropivacaine) and control (normal saline) groups. 2- Evaluation and comparison of postoperative hemorrhage in case (ropivacaine) and control (normal saline) groups. 3- Evaluation and comparison of the starting time of postoperative oral nutrition in case (ropivacaine) and control (normal saline) groups.

Design

(A one-blind, randomized clinical trial with a control group, and parallel groups)

Settings and conduct

50 children under the age of 15 years with tonsillar hypertrophy referring to Tabriz Children Hospital for tonsillectomy were randomly divided into two groups of 25 cases (ropivacaine) and 25 controls (normal saline). Patients, clinical caregivers, and data analyst will not be aware of grouping.

Participants/Inclusion and exclusion criteria

50 children under the age of 15 years with tonsillar hypertrophy referring to Tabriz Children Hospital for Tonsillectomy will be included in the study after obtaining informed consent from their parents. Children under the supervision of a specialist will undergo tonsillectomy with anesthesia class 1 and 2. Children who have an anesthetic class of more than 2 or have more than an hour of surgery duration, or suffering from post-operative airway complications will be excluded.

Intervention groups

Case group (Ropivacaine): Ropivacaine 0.5% immediately after intubation as well as at the end of the surgery will be administered in the form of a puff on each tonsil. Control group: Normal saline immediately after intubation as well as at the end of the surgery will be administered in the form of a puff on each tonsil.

Main outcome variables

Pain intensity; prevalence of bleeding; time of onset of postoperative oral nutrition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100527004041N16**
Registration date: **2019-05-08, 1398/02/18**
Registration timing: **retrospective**

Last update: **2019-05-08, 1398/02/18**
Update count: **0**

Registration date

2019-05-08, 1398/02/18

Registrant information

Name
Mahin Seyedhejazi

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2019-02-20, 1397/12/01

Actual recruitment end date

2019-03-11, 1397/12/20

Trial completion date

2019-05-21, 1398/02/31

Scientific title
The Effect of Topical Ropivacaine Spray on Relief of Post-Tonsillectomy Pain in Children

Public title
The Effect of Ropivacaine in Tonsillectomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children under 15 years of age Suffering from Tonsillar hypertrophy Referring to Tabriz Children Hospital for tonsillectomy
Exclusion criteria:
The anesthetic class of more than 2 Duration of surgery of more than an hour Airways complications after surgery
Age
To **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization of the samples was done by using online software available at www.stat.vbc.ca/nrolin/statssize/bz.html.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients, clinical caregivers, and data analyzers will not aware of grouping.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2019-03-11, 1397/12/20
Ethics committee reference number
IR.TBZMED.REC.1397.1053

Health conditions studied

1

Description of health condition studied
Tonsillectomy
ICD-10 code
J35.1
ICD-10 code description
Hypertrophy of tonsils

Primary outcomes

1

Description
Pain severity
Timepoint
One hour after recovery
Method of measurement
By Visual Analogue Scales

2

Description
Incidence of bleeding
Timepoint
One hour after recovery
Method of measurement
View and questionnaire

3

Description
Oral feeding initiation time
Timepoint
One hour after recovery, until the discharge
Method of measurement
View and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A 0.5% ropivacaine (ropivacaine hydrochloride, 5 mg/ml; MOLTENI farmaceutici, Italy)

spray immediately after intubation as well as at the end of the surgery will be administered in the form of a puff (0.1 ml) on the surface of each tonsil.

Category

Other

2

Description

Control group: A normal saline spray immediately after intubation as well as at the end of the surgery will be administered in the form of a puff on the surface of each tonsil.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Mahin Seidhejazie

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Sheshgelan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Web page address

https://researchvice.tbzmed.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Farhad Khayat Zahiri

Position

Fellowship of Pediatric Anesthesia

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahin Seidhejazie

Position

professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mahin Seidhejazie
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Latest degree
Specialist
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available