

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 2252

Email address

seidhejazie@tbzmed.ac.ir

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

Street address

Sheshgelan Street

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2256

Fax

+98 41 3526 2256

Email

seidhejazie@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3335 7310

Fax

+98 41 3334 4280

Email

sina_raeisi7007@yahoo.com

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

Anesthesiology

Street address

Sheshgelan Street

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2256

Email

farhad_zahiri@yahoo.com

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

Anesthesiology

Street address
Sheshgelan Street
City
Tabriz
Province
East Azarbaijan
Postal code
5136735886
Phone
+98 41 3526 2250
Email
seidhejazie@tbzmed.ac.ir

Person responsible for updating data

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
Anesthesiology
Street address
Sheshgelan Street
City
Tabriz
Province

East Azarbaijan
Postal code
5136735886
Phone
+98 41 3526 2250
Email
seidhejazie@yahoo.com

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