

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of peritonsillar infiltration of Bupivacaine and Dexamethasone effect on pediatric post tonsillectomy pain reduction

Protocol summary

Study aim

Evaluation of peritonsillar infiltration of Bupivacaine and Dexamethasone effect on pediatric post tonsillectomy pain reduction

Design

Single blind clinical trial, randomized with random numbers table, allocation concealment: using of Sequentially numbered, sealed, opaque envelopes, with control group, with factional groups on 70 children between ages of 4-15.

Settings and conduct

Study will be done, in surgery department of Sabzevar Heshmatie hospital. Patients who will enter in study, without awareness of which group they are attending, they will be operate. After anesthesia and 10 minutes before surgery, bupivacaine and dexamethasone will be direct injected to peritonsillar. When the operate will be ended, patients will be observed at 24 hours. During the hospitalization, the pain will be recorded three times.

Participants/Inclusion and exclusion criteria

Entry requirements: Tonsillectomy surgery indication Age between 4-15 years No entry requirements: Asthma Chronic analgesic drugs use Usage of analgesic drugs at 24 hours before surgery Inability to connect with others Chronic disease Peritonsillar abscess history Present upper respiratory infection

Intervention groups

Intervention group: Patients of this group will receive Bupivacaine with Dexamethasone as a direct peritonsillar injection, before Surgery. 10 minutes later surgery will be start. Control group: Patients of this group will not receive Bupivacaine with Dexamethasone, before Surgery.

Main outcome variables

pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190406043179N1**

Registration date: **2019-08-05, 1398/05/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-05, 1398/05/14**

Update count: **0**

Registration date

2019-08-05, 1398/05/14

Registrant information

Name

Kaveh Ghajari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3765 7960

Email address

ghajarik90@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-21, 1398/04/30

Expected recruitment end date

2019-08-19, 1398/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of peritonsillar infiltration of Bupivacaine and Dexamethasone effect on pediatric post tonsillectomy pain reduction

Public title

Evaluation of Bupivacaine and Dexamethasone effect on Post Tonsillectomy Pain reduction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Tonsillectomy surgery indication Age between 4-15 years

Exclusion criteria:

Asthma Chronic analgesic drugs use Usage of analgesic drugs at 24 hours before surgery Inability to connect with others Chronic disease Peritonsillar abscess history Present upper respiratory infection

Age

From **4 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization method: Simple randomization
Randomization unit: individual Randomization tool: with using a random numbers table
How to create a random sequence: using a random numbers table to read it from top to bottom and the even numbers belong to intervention group and the odd numbers belong to control group.
Allocation concealment: using of Sequentially numbered, sealed, opaque envelopes, In this way that the numbers obtained by the random numbers table will be written on the cards respectively. each card will be put inside sealed opaque envelopes. Then envelopes will be numbered and placed in boxes respectively. In the next stage, the patients will enter the group by taking the envelopes respectively (Preparation of the envelopes will be done by the secretary and the physician will not be informed of them).

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will not be informed about which group they are attending, until data collection will be finished.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Shahr blvd, Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.MEDSAB.REC.1397.126

Health conditions studied

1

Description of health condition studied

Pediatric post tonsillectomy pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pediatric post tonsillectomy pain,

Timepoint

6, 12, 24 hours after surgery

Method of measurement

Using of Visual Pain Analog Scale by executor of plan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: there are 35 of attended patients (according to the criteria of entering the study), who they will receive Bupivacaine 5 mg (France Astra Zeneca company) with Dexamethasone (Iran Hormon company) 0.3 mg per kilogram of patient weight as a direct peritonsillar injection, before Surgery. 10 minutes later surgery will be start.

Category

Treatment - Other

2

Description

Control group: there are 35 of attended patients (according to the criteria of entering the study), who they will not receive any Bupivacaine and Dexamethasone before surgery (According to the references, if patients did not get drug, they will not harm and this is acceptable).

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Heshmatie hospital

Full name of responsible person

Dr. Seyyed Morteza Rasti Sani

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Asad abadi Ave.

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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Ghorat

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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

Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Kaveh Ghajari

Position

Medicine student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Mohamad Shuride Yazdi

Position

Consultant

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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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