Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative effect of local injection of bupivacaine with lidocain and epinephrine composition on post tonsillectomy pain

Protocol summary

Summary

The purpose of this double-blind randomized clinical trial study, is to determine and compare the effect of local injection of bupivacaine and lidocain and epinephrine composition on post tonsillectomy pain. Case study samples, are 4-10 year- old children candidate for tonsillectomy, admitted in ENT ward in Imam Sajjad hospital. Samples with Inclusion criteria, will be chosen non-random and then will be placed in three groups by random blocks allocation and this continue until the samples are complete. Sample size is 29 patients in each group (a total of 87 people). Gathering Information will be done by direct observation, demographic check list and Wong-Baker pain scale. After Ethics committee of Yasuj University of Medical Sciences approval and parents informed consent, all patients will be under similar general anesthesia method. The method of cold knife dissection will be similar in all patients. 5 minutes before the surgical incision, in the first group, 2 ml of bupivacaine 0.125, in the second group 2 ml of 1% lidocaine combined and epinephrine 1: 200,000, will be injected locally in the bed and around the tonsils and tonsillectomy will be done. There is no intervention in Group 3. After surgery and transferring the patients to the ENT ward, pain will be measured 2 hours, 4 hours and 6 hours after surgery with Wong-Baker pain scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072529065N1**
Registration date: **2017-06-08, 1396/03/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-08, 1396/03/18

Registrant information

Name
Mahin Roozitalab
Name of organization / entity
Yasuj University of Medica Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Yasuj University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of local injection of bupivacaine with lidocain and epinephrine composition on post tonsillectomy pain

Public title

The effect of bupivacaine with lidocain and epinephrine composition on the pain in patients undergoing tonsillectomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patient candidate for elective tonsillectomy; children aged 4 to 10 years; consent of the parents; lack of co-morbidities; negative history of surgery; The ability to verbal communication; cognitive and Mental health. Exclusion criteria: metabolic and endocrine diseases; coagulation disorders; mental retardation; positive history of allergy to drugs; pre-tonsilar abscess; hypertension; psychotic disorder; chronic pain; want to withdraw the study; creates complications in patients like bleeding, Late recovery (2 hours post operation); receiving narcotic drug during study; obesity
Age
From **4 years** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **87**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Block Randomize Allocation

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Yasuj University of Medical Sciences
Street address
Yasuj University of Medical Sciences
City
Yasuj
Postal code
Approval date
2016-01-02, 1394/10/12
Ethics committee reference number
ir.yums.rec.1394.121

Health conditions studied

1

Description of health condition studied
Tonsilectomy
ICD-10 code
J35
ICD-10 code description
Chronic diseases of tonsils and adenoids

Primary outcomes

1

Description
pain
Timepoint
2,4,6 post operation surgery
Method of measurement
wong- baker scale

Secondary outcomes

1

Description
Vital Signs
Timepoint
2,4,6 Post Operation Surgery
Method of measurement
Sphygmomanometer,Thermometer

Intervention groups

1

Description
Intervention group: After induction of anesthesia, cold knife tonsillectomy will be performed. 5 minutes before the surgical incision, in the first group 2 mL of 0.125 bupivacaine, in the second group 2 mL of 1% lidocaine and 1:200,000 epinephrine composition, will be injected locally on the bed and around the tonsils with a single technique as a fan of the upper and lower poles of the tonsils and tonsillectomy will be done. The duration of anesthesia and surgery asses, also patients' vital signs will be recorded before induction of anesthesia, during surgery and in the recovery room. After surgery and transferring the patients of recovery room to the ENT ward, patients' Vital Signs and demographic data collected by check list and pain will be measured 2 hours, 4 hours and 6 hours after surgery with Wong-Baker Pain Scale.
Category
Treatment - Drugs

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Description
Control group: After induction of anesthesia, cold knife tonsillectomy will be performed. There is no intervention in Group 3. The duration of anesthesia and surgery asses, also patients' Vital Signs will be recorded before

induction of anesthesia, during surgery and in the recovery room. After surgery and transferring the patients of recovery room to the ENT ward, patients' Vital Signs and demographic data collected by check list and pain will be measured 2 hours, 4 hours and 6 hours after surgery with Wong-Baker Pain Scale.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajad(A) Hospital

Full name of responsible person

Mahin Roozitalab

Street address

Paramedicin Faculty, Yasuj University of Medical Sciences,

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Yasuj University of Medical Sciences

Full name of responsible person

Hossien Marry Oryad

Street address

Vice chancellor for research of Yasuj University of Medical Sciences, University of Medical Sciences, Yasuj

City

Yasuj

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research of Yasuj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences, Yasuj, Iran

Full name of responsible person

Mahin Roozitalab

Position

MSC in Medical Surgical Nursing/ Faculty Member

Other areas of specialty/work

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Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty