Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of Bupivacaine on post tonsillectomy pain

Protocol summary

Summary

Aim of the study was evaluation of the effect of Bupivacaine on post tonsillectomy pain. This was a double blind randomized clinical study in a single center (Dastgheib University Hospital Shiraz-Iran). Trained anesthesia nurse and statistician as assessors have been blinded. Patients were divided in three groups; Group 1 (100 patients): Bupivacaine injection before incision. Group 2 (100 patients): Bupivacaine injection after excision of tonsils. Group 3 (100 patients): Bupivacaine injection was not used. The groups were also allowed to take oral acetaminophen if needing. Inclusion criteria were: 1) age range 3-15 years old; 2) patients who undergo tonsillectomy due to three or more severe recurrent attacks of tonsillitis within each two consecutive years. Exclusion criteria were: 1) pre operative medical problems such as asthma, diabetes, coagulation disorders, cardiovascular disease, basic metabolic disorder, immune system deficiency and chronic liver or renal disease; 2) Inadequate follow-up and incomplete questionnaires. Primary outcome was pain within 24 hours after operation. Pain had been evaluated by Visual Analog Scale by trained anesthesia nurse in the ward.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011615496N4**
Registration date: **2015-09-19, 1394/06/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-19, 1394/06/28

Registrant information

Name

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Name of organization / entity

Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Shiraz University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Bupivacaine on post tonsillectomy pain

Public title

The effect of local pain killer "Bupivacaine" on post tonsillectomy pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) age range 3-15 years old; 2) patients who undergo tonsillectomy due to three or more severe recurrent attacks of tonsillitis within each two consecutive years. Exclusion criteria: 1) pre operative medical problems such as asthma, diabetes, coagulation disorders, cardiovascular disease, basic metabolic

disorder, immune system deficiency and chronic liver or renal disease; 2) Inadequate follow-up and incomplete questionnaires.

Age
From **3 years** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand Street

City
Shiraz

Postal code

Approval date
2006-02-12, 1384/11/23

Ethics committee reference number
CT-84-2682

Health conditions studied

1

Description of health condition studied
Tonsillectomy

ICD-10 code
J35.1, J35

ICD-10 code description
Hypertrophy of tonsils, Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description
Post-tonsillectomy pain

Timepoint
within 24 hours after operation

Method of measurement
Pain had been evaluated by Visual Analog Scale by trained anesthesia nurse in the ward.

Secondary outcomes

empty

Intervention groups

1

Description
Group 1-(Intervention Group): 10 ml of Bupivacaine 5 mg/ml in each site of operation-totally 20 ml- was injected before incision. After surgery, this group was also allowed to take oral acetaminophen)children less than 12 years: 10-15 mg/kg/dose, each 6 hours and children 12-15 years: 325-650 mg, each 6 hours) if needed.

Category
Treatment - Drugs

2

Description
Group 2-(Intervention Group): 10 ml of Bupivacaine 5 mg/ml in each site of operation-totally 20 ml- was injected after excision of tonsils. After surgery, this group was also allowed to take oral acetaminophen)children less than 12 years: 10-15 mg/kg/dose, each 6 hours and children 12-15 years: 325-650 mg, each 6 hours) if needed.

Category
Treatment - Drugs

3

Description
Group 3-(Control Group): Bupivacaine injection was not used. After surgery, this group was also allowed to take oral acetaminophen (children less than 12 years: 10-15 mg/kg/dose, each 6 hours and children 12-15 years: 325-650 mg, each 6 hours) if needed.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Dastgheib Hospital

Full name of responsible person
Dr. Mohammad Faramarzi
Street address
Hafez Street, Next to National Garden
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Shiraz University of Medical Sciences, Zand Street
City
Shiraz
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, Shiraz 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
Center for Development of Clinical Studies, Vice Chancellor of Research and Technology, Shiraz Unive
Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

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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