

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

Sareh Roosta

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

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Hafez Street, Next to National Garden

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

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Full name of responsible person

Dr. Mohammad Faramarzi

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Web page address**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

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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

Sareh Roosta

Position

MSc of Biostatistics

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Center for Development of Clinical Studies of Nemazee Hospital, Vice Chancellor of Research and Tech

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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