

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of intravenous fentanyl and infiltration of bupivacaine-clonidine in decreasing post tonsillectomy pain and complications in children

Protocol summary

Summary

The aim of this study is to compare analgesic efficacy of local injection of clonidine + bupivacaine with intravenous fentanyl for postoperative tonsillectomy. In this double-blind randomized clinical trial, after local ethical committee and Tabriz university research center approval and obtaining informed parental consent, 140 patients (3-12 y) with American society of Anesthesiologists (ASA) status I and II, without upper respiratory tract infection and anemia, undergoing tonsillectomy, were prospectively enrolled from Tabriz Children Hospital during a one-year period of time. The patients were randomized in two 70-patient groups received intravenous fentanyl (1µg/kg) (group F) or infiltration of bupivacaine 0.25% (0.1mg/kg) plus clonidine (1µg/kg) (group BC) after anesthesia induction. The induction and maintenance of anesthesia will be same in both groups. The post-operative pain will be evaluated by Wong-Baker Face Pain Scale (FPS). The hemodynamic changes, as well as possible complications will also be determined during first 24 hours hospital stay. The observer and the patients will be blind to the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903064041N1**
Registration date: **2011-04-14, 1390/01/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-14, 1390/01/25

Registrant information

Name

Mahin Seyedhejazi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-04-01, 1389/01/12

Expected recruitment end date

2011-01-01, 1389/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous fentanyl and infiltration of bupivacaine-clonidine in decreasing post tonsillectomy pain and complications in children

Public title

local injection in decreasing post tonsillectomy pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : parent approval; age between 3-12 years old. Exclusion criteria: coexisting diseases like sever

common cold ,anemia.
Age
From **3 years** old to **12 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **140**
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
Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences
City
Tabriz
Postal code
5136735886
Approval date
1990-01-01, 1368/10/11
Ethics committee reference number
5/4/9503

Health conditions studied

1
Description of health condition studied
pain after adenotonsilectomy
ICD-10 code
J35.3
ICD-10 code description
Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1
Description

pain
Timepoint
2, 4, 6, 8 hours after operation
Method of measurement
Face Pain Scale

Secondary outcomes

1
Description
analgesic usage
Timepoint
2, 4, 6, 8 hours after operation
Method of measurement
mg/kg

Intervention groups

1
Description
intervention: infiltration of local bupivacaine 0.25% (0.1mg/kg) and clonidine (0.1ml/kg) in the base of tonsils bilaterally
Category
Treatment - Drugs

2
Description
control: intravenous fentanyl (1µg/kg)
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
operating room, Tabriz Children Hospital
Full name of responsible person
Dr. Mahin Seyedhejazi
Street address
Tabriz Children Hospital
City
Tabriz

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mahin Seyedhejazi
Street address
Tabriz Children Hospital
City

Tabriz

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

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mahin Seyedhejazi

Position

Associate Professor of Anesthesia

Other areas of specialty/work

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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