

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the Effect of Alfentanil and Remifentanil on QT Interval in Septoplasty with Local Epinephrine

Protocol summary

Summary

Objectives: To compare the effects of remifentanil and alfentanil on the corrected QT interval in Septoplasty surgery under general anesthesia followed by local injection of epinephrine. ECG QT interval was recorded at specific time intervals in patients who are admitted to Dastghib hospital (referral center in Shiraz, southern Iran) for Septoplasty surgery under general anesthesia, and local injection of epinephrine. Method: 84 patients were randomly divided into two groups. Patients in treatment group received short acting narcotics (remifentanil and alfentanil) while, ECG QT interval recorded at specific time intervals. Inclusion criteria included patients aged 18-50 years who are classified as ASA I-II (America Society of Anesthesiologists) under general anesthesia for septoplasty and local injection of epinephrine are enrolled the study. Patients were excluded from the study if any of the following criteria were present: Use of any drug affecting QT interval in last 14 days including: tricyclic antidepressants (TCAs), anti-arrhythmic drugs, β blockers and calcium channel blockers, idiopathic or acquired QTc prolongation in preoperative electro cardiogram (ECG) (QTc >440 ms), existence of arrhythmia (e.g. bundle branch block, preexcitation syndrome or AV nodal arrhythmia), structural heart disease, electrolyte disturbance, hypo or hyperthyroidism, obesity with BMI >30, diabetic neuropathy, any rhythm besides sinus rhythm in baseline ECG, allergy to propofol, egg and soya bean, need to use of β blockers or volatiles for controlling of excessive bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020816524N1**

Registration date: **2014-11-30, 1393/09/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-30, 1393/09/09

Registrant information

Name

Fatemeh Tubaei

Name of organization / entity

Shiraz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Alfentanil and Remifentanil on QT Interval in Septoplasty with Local Epinephrine

Public title

Effect of Alfentanil and Remifentanil on QT Interval

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with physical status class I-II, based on the classification of the American Society of Anesthesiologists (ASA) and the age up to 50 years undergoing septoplasty. Exclusion criteria: the use of any effective drug on QT interval in 14 days before surgery (TCA); beta antagonist, anti-arrhythmic, the calcium channel blocker; QTc more than 440 m/s; The existence of branches blocks, arrhythmia (preexcitation syndrome); Structural heart disease.; electrolyte imbalance; hyper or hypothyroid patients. Extreme Obesity BMI 30 >; Diabetic neuropathy; Any non-sinus rhythm in EKG; A history of sensitivity to propofol, egg and soy.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Central Building of Shiraz University Of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2013-10-08, 1392/07/16

Ethics committee reference number

cp-p-92-6118

Health conditions studied

1

Description of health condition studied

QT Prolongation

ICD-10 code

R 94.3

ICD-10 code description

Electrocardiogram [ECG][EKG]

Primary outcomes

1

Description

QT interval

Timepoint

Prioperative /Six times

Method of measurement

EKG

Secondary outcomes

1

Description

Heart Rate Monitoring

Timepoint

Six Times Perioperative

Method of measurement

EKG

Intervention groups

1

Description

In intervention group we use alfentanil 20-25 microgram/kg in induction and with rate of 0.5-2 microgram/kg/min in maintenance. In control group remifentanil is used with dose of 1-2 microgram/kg in induction and infused with rate of 0.2-0.25 microgram/kg/min in maintenance of anesthesia.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dastgheib Hospital

Full name of responsible person

Fatemeh Toobaei

Street address

Hafezieh Square, next to Bagh Melli

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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 Seed Basir Hashemi

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Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of 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**

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Toobaei

Position

Physician, Anesthesiology resident

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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