

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effects of Remifentanil and Alfentanil on QT interval in elective surgery under general anaesthesia

Protocol summary

Summary

The aim of this study is to compare the effects of two widely used narcotics (remifentanil and alfentanil) in general anesthesia Methods: Sixty female patients , aged 18- 35, scheduled for elective otolaryngologic operations under general anesthesia with American Society of Anesthesiologists physical status I (ASA I) without any heart disease (arrhythmia , valvular), were randomly allocated to two groups. In both groups bolus dose of remifentanil and alfentanil were followed by infusion of the same drugs . Anesthesia was induced with propofol , muscle relaxation facilitated by cisatracurium .ECG (Three lead electrocardiogram), heart rate and non-invasive blood pressures were recorded at the following times: before and 90 seconds after the induction of anesthesia, 1 min. and 5 min. after endotracheal intubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210172310N2**

Registration date: **2014-01-20, 1392/10/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-20, 1392/10/30

Registrant information

Name

MANSOOR MASJEDI

Name of organization / entity

SHIRAZ UNIVERSITY OF MEDICAL SCIENCES

Country

Iran (Islamic Republic of)

Phone

+98 71 1626 1562

Email address

masjedi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences (SUMS) -This study has received research grant from Vice-Chancellery of Research and Technology of Shiraz University of medical sciences (grant No. CT-87-4291) .

Expected recruitment start date

2008-06-03, 1387/03/14

Expected recruitment end date

2011-06-06, 1390/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Remifentanil and Alfentanil on QT interval in elective surgery under general anaesthesia

Public title

Effect of opioids on heart under general anaesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-35 years; ASA - PS (American Society of Anesthesiologist- Physical Status) : I ; Elective ENT (Ear-Nose-Throat) operation under general anesthesia. Exclusion criteria : Abnormal serum electrolytes, cardiovascular or psychiatric problems; idiopathic or acquired prolonged QT interval;anticipated difficulty in tracheal intubation ; patients taking any medication affecting QTc interval (e.g. :tricyclic

antidepressant, antidysrhythmics, β -adrenergic antagonists, calcium channel blockers); existence of cardiac valvular disease; any cardiac rhythm abnormality; diabetes mellitus; pregnancy; obesity (body mass index > 30) and hypersensitivity reaction to egg, fish or soya bean.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Shiraz University of Medical Sciences- Ethics Committee

Street address

Zand street

City

shiraz

Postal code

Approval date

2011-03-28, 1390/01/08

Ethics committee reference number

CT-87-4291

Health conditions studied

1

Description of health condition studied

conduction disorder

ICD-10 code

145.8

ICD-10 code description

Other specified conduction disorders

2

Description of health condition studied

General anesthesia

ICD-10 code

146.9

ICD-10 code description

Cardiac arrest, unspecified

Primary outcomes

1

Description

QT interval

Timepoint

Before and 90 seconds after induction of anesthesia, 1 and 5 minutes after endotracheal intubation

Method of measurement

Electrocardiograph

Secondary outcomes

1

Description

Heart rate

Timepoint

Before and 90 seconds after induction of anesthesia, 1 and 5 minutes after endotracheal intubation

Method of measurement

Operating room monitor

2

Description

Blood pressure

Timepoint

Before and 90 seconds after induction of anesthesia, 1 and 5 minutes after endotracheal intubation

Method of measurement

Operating room monitor

Intervention groups

1

Description

In one group, as anesthetic premedication, bolus dose of intravenous remifentanyl (2 μg / kg over 60 seconds) will be given followed by its infusion (0.15 μg / kg / min) throughout maintenance of anesthesia. In all patients, anesthesia will be induced by propofol (2 mg / kg) and muscle relaxation by cisatracurium (0.1 mg / kg)

Category

Prevention

2

Description

In the other group, as anesthetic premedication, bolus dose of alfentanil (20 μg / kg over 60 seconds) will be

followed by its infusion (0.25 µg / kg / min)throughout maintenance of anesthesia . Anesthesia will be induced with propofol (2.5 mg / kg) and muscle relaxation facilitated by cisatracurium (0.1 mg/kg)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University affiliated hospitals

Full name of responsible person

Mansoor Masjedi

Street address

No. 603,5 th avenue , Khalili street , Mollasadra street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Mohammad Ali Sahmeddini

Street address

Zand st, Central building of the University

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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 Anesthesiology and Critical Care Research Center, Department Of Anesthesia, Medical school ,

Full name of responsible person

Mansoor Masjedi,

Position

MD,FCCM (Fellowship of critical care medicine)

Other areas of specialty/work

Street address

No. 603,5 th avenue , Khalili street , Mollasadra street

City

Shiraz

Postal code

71936/34153

Phone

+98 71 1647 4270

Fax

+98 71 1647 4270

Email

masjedi@sums.ac.ir , mansoormasjedi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences (SUMS)

Full name of responsible person

Mohammad Hosein Eghbal

Position

MD , Fellowship of anesthesia for organ transplant

Other areas of specialty/work

Street address

Anesthesia Dept. , Faghihi hospital , Zand street

City

Shiraz

Postal code

Phone

+98 71 1647 4270

Fax

+98 71 1647 4270

Email

mheghbal@sums.ac.ir ,
Mohammadhoseineghbal@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz Anesthesiology and Critical Care Research Center, Shiraz University of Medical Sciences (S

Full name of responsible person

Mansoor Masjedi

Position

MD , FCCM (fellowship of critical care medicine)

Other areas of specialty/work

Street address

No. 603,5 th avenue , Khalili street , Mollasadra street

City

Shiraz

Postal code

71936/34153

Phone

+98 71 1647 4270

Fax

+98 71 1647 4270

Email

masjedi@sums.ac.ir , mansoormasjedi@yahoo.com

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