

# 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,  $\beta$ -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  $\mu\text{g}$  / kg over 60 seconds) will be given followed by its infusion (0.15  $\mu\text{g}$  / 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  $\mu\text{g}$  / kg over 60 seconds) will be

followed by its infusion ( 0.25 µg / kg / min )through 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

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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## Person responsible for updating data

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Mansoor Masjedi

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**Email**

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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*