

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

Comparing the effect of fentanyl, sufentanil and alfentanil on cardiovascular response after tracheal intubation in opiate addicted patients after elective surgeries.

Protocol summary

Summary

According to our knowledge addicted patients are resistant to analgesic effects of opioids, thus the aim of this study was to clarify which of opioids that routinely used in anesthesia could reduce the cardiovascular response to intubation. In this randomized double blind study 93 patients who were scheduled for elective surgery under general anesthesia, allocated in three groups according to the type of opioid administered for them to induce anesthesia, alfentanil 20 µg/kg, sufentanil 0.2 µg/kg, fentanyl 2 µg/kg. Regardless of the type of the opioid propofol 20 mg/kg, atracurium 0.5 mg/kg and midazolam 1-2 mg were administered in all 3 groups. Non-Invasive blood pressure and heart rate was measured before induction of anesthesia, 3 minutes after it and immediately after tracheal intubation. Systolic, diastolic, mean blood pressure and heart rate at each of aforementioned times was compared between three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011721383N4**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

Name

Amir Saber Tanha

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 2778

Email address

dr.saber@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences.

Expected recruitment start date

2016-01-13, 1394/10/23

Expected recruitment end date

2016-09-13, 1395/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of fentanyl, sufentanil and alfentanil on cardiovascular response after tracheal intubation in opiate addicted patients after elective surgeries.

Public title

Comparing the effect of fentanyl, sufentanil and alfentanil on hemodynamic changes after tracheal intubation in opiate addicted patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all opiate addicted patients who were scheduled to undergo elective surgeries with tracheal intubation. Exclusion criteria: hypertension; non elective

surgeries; diabetes mellitus; dysautonomia; heart failure; severe hemorrhage; severe hemodynamic instability.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **93**

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

Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghafari Street, Birjand, Iran.

City

Birjand

Postal code

9717853577

Approval date

2016-01-11, 1394/10/21

Ethics committee reference number

Ir.bums.1394.85

Health conditions studied

1

Description of health condition studied

Cardiovascular response

ICD-10 code

B57.0

ICD-10 code description

Acute Chagas disease with heart involvement

Primary outcomes

1

Description

Blood pressure

Timepoint

Before induction of anesthesia, 3 minutes after induction of anesthesia, after intubation

Method of measurement

In mmhg with digital manometer

2

Description

Heart rate

Timepoint

Before induction of anesthesia, 3 minutes after induction of anesthesia, after intubation

Method of measurement

Beat per minute with electrocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Administration of alfentanil 20 microgram per kilogram of body weight before induction of anesthesia.

Category

Prevention

2

Description

Administration of fentanyl 2 microgram per kilogram of body weight before induction of anesthesia.

Category

Prevention

3

Description

Administration of sufentanil 0.2 microgram per kilogram of body weight before induction of anesthesia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital of Birjand University of Medical Sciences.

Full name of responsible person

Dr. Amir Saber Tanha

Street address

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Asghar Zarban

Street address

Birjand University of Medical Sciences, Ghafari Street,
Birjand, Iran

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Dr. Amir Saber Tanha

Position

Assistant professor of anesthesia

Other areas of specialty/work

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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