Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
۹۷۱۷۸۵۳۵۷۷

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 fentanyle 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
Assisstant professor of anesthesia
Other areas of specialty/work
Street address
Birjand University of Medical Sciences, Ghafari Street, Birjand.
City
Birjand
Postal code
Phone
+98 56 3243 2778
Fax
Email
amirsaber63@gmail.com
Web page address

Person responsible for scientific 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
Street address
Birjand University of Medical Sciences, Ghafari Street, Birjand
City
Birjand
Postal code
Phone
+98 56 3243 2778
Fax
Email
amirsaber63@gmail.com
Web page address

Person responsible for updating data

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
Street address
Birjand University of Medical Sciences, Ghafari Street, Birjand
City
Birjand
Postal code
Phone
+98 56 3243 2778
Fax
Email
amirsaber63@gmail.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