Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of hemodynamic indices during endotracheal intubation after receiveing Clonidine and Fentanyl premedication in opium dependent patients

Protocol summary

Summary

The aim of this study is to compare the effect of Clonidine premedication with Fentanyl on hemodynamic changes after endotracheal intubation in opium dependent patients. In this clinical trial, 60 opium dependent patients whom refer to the operating room of 15 Khordad hospital of Gonabad for elective surgery who require endotracheal intubation are randomly assigned into group Fentanyl(1 microgram/kg, 5 min before intubation given intravenously) and Clonidine(3-5 microgram/kg, 60 min before intubation given oraly). Inclusion criteria: Age 18 to 65 years old, opium dependent patients who are candidate for elective surgery under general anesthesia with endotracheal intubation who are in ASA class 1 and 2. Exclusion criteria: Any cardiovascular problems and arrhythmias during intubation, Over once to attempt intubation that may take more than 20 seconds. the outcomes that will be measured is hemodynamic changes(systolic blood pressure, diastolic blood pressure and heart rate) after intubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030516854N1**
Registration date: **2014-07-11, 1393/04/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-07-11, 1393/04/20

Registrant information

Name

Ali Reza Talai

Name of organization / entity

Gonabad University of Medical

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Gonabad University of Medical Sciences

Expected recruitment start date

2013-10-07, 1392/07/15

Expected recruitment end date

2014-06-05, 1393/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic indices during endotracheal intubation after receiveing Clonidine and Fentanyl premedication in opium dependent patients

Public title

The comparison of effect of clonidine and fentanyl premedication on blood pressure and pulse rate changes in opium depended patient after indotracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age range of 18-65 years old;

Candidate for elective surgery and those who were in ASA class of 1 and 2؛ The drug-dependent patients based on our definitions؛ No history of other addictive materials such as alcohol and psychoactive drugs؛ ptients should not have any anxiety disorders. Exclusion criteria: Any cardiovascular problems and arrhythmias during intubation؛ Over once to attempt intubation that may take more than 20 seconds؛ Any problem during intubation and surgery in which necessary interventions and desired measurements be impossible.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The samples were randomly divided into two groups of Fentanyl and Clonidine

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Gonabad University of Medical Sciences

Street address
Gonabad University of Medical sciences , Dr Mehdizade street , Pardise

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Gonabad

Postal code
9691793718

Approval date
2014-03-12, 1392/12/21

Ethics committee reference number
gmu.rec.1392.52

Health conditions studied

1

Description of health condition studied
opioid dependency

ICD-10 code
F10

ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description
Systolic blood pressure and diastolic blood pressure

Timepoint
Before intubation, immediately after intubation and 5 minutes after intubation

Method of measurement
Measurement of blood pressure using a mercury sphygmomanometer

2

Description
Heart rate

Timepoint
Before intubation, Immediately after intubation and 5 minutes after intubation

Method of measurement
Radial pulse counting with second time

Secondary outcomes

empty

Intervention groups

1

Description
In the clonidine group, Patients are given oral clonidine with dose of 3 – 5 microgram/kg, 60 minutes before endotracheal intubation.

Category
Treatment - Drugs

2

Description
in the Fentanyl group, Fentanyl 1 microgram/kg is injected intravenously 5 minutes before indotracheal intubation

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

15 Khordad Hospital Beydokht
Full name of responsible person
Ali Reza Talai
Street address
15 Khordad Hospital Beydokht, shafa square, Gonabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Gonabad University of Medical Sciences
Full name of responsible person
Dr. Ali Mohammadpour
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Gonabad
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, Gonabad 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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