

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of hemodynamic indices during endotracheal intubation after receiving 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 orally). 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 receiving 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 , Paradise

City

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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Medical Sciences
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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 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