

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of pretreatment with clonidine on propofol consumption in opium abuser and non-abuser patients undergoing elective leg surgery

Protocol summary

Summary

Comparison of effect of pretreatment with clonidine on propofol consumption in opium abuser and non-abuser patients undergoing elective leg surgery. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study. Study population: patient between 18-65 y/o addict & non addict with ASA class 1&2 undergoing elective leg surgery with max time of surgery<180min in imam hossein hospital. Inclusion criteria: ASA classification score 1 or 2 (I or II); age range of 18 to 65 years and maximum length of surgery up to 180 min. Exclusion criteria: patient disagreement; hemodynamic instability and maximum length of surgery>180min. Sample size: 160 cases. Intervention: In a randomized clinical trial, 160 cases were selected and assigned into the study groups. 80 patients were selected among the opium abusers and 80 were selected among the non-abuser patients. Then, both groups were randomly assigned and divided into one of the 2 groups, either receiving or not receiving clonidine. The patients were anesthetized using the same predetermined method, The depth of anesthesia was controlled and kept between 40 and 60 by recording the Bispectral index. If any deviation was noted, the level of anesthesia was corrected to reach the determined range. Finally, after termination of the surgery, the results for the length of operation, the detailed BIS number recordings, the total administered dose of propofol, the length of anesthesia, and the patients, Recovery time, Intraoperative bleeding, recorded. Time duration: 60 day. Outcome: clonidine decrease propofol consumption in addict & non addict patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202159026N1**

Registration date: **2012-04-05, 1391/01/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-04-05, 1391/01/17

Registrant information

Name

Davood Ommi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 7756 7840

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mjabbarym@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pretreatment with clonidine on propofol consumption in opium abuser and non-abuser patients undergoing elective leg surgery

Public title

Effect of clonidine on intraoperative consumption of propofol

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria patient informed written consent for entering study; American Society of Anesthesiologists (ASA) classification score 1 or 2 (I or II); age range of 18 to 65 years and maximum length of surgery up to 180 minutes Exclusion criteria patient disagreement; ASA class>2; SBP>140mmhg or SBP<90mmhg; maximum length of surgery>180min; age<18y or age>65y; cardiac arrhythmias; SaO2<90%; history of egg or propofol sensitivity; multiple trauma; addict in withdrawal phase coagulopathy.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences Ethics Committee

Street address
Velenjak

City
Tehran

Postal code

Approval date
2011-01-23, 1389/11/03

Ethics committee reference number
400/8014

Health conditions studied

1

Description of health condition studied
general anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intraoperative consumption of propofol

Timepoint
During operation

Method of measurement
miligram

Secondary outcomes

1

Description
Intraoperative bleeding

Timepoint
During operation

Method of measurement
Mililiter

2

Description
Recovery time

Timepoint
At the end of anesthesia

Method of measurement
Minutes

Intervention groups

1

Description
In first Intervention(case) group (non addicted)& second Intervention(case) group (addicted) tab clonidine(5mic/kg)90min before operation will prescribe and then The patients will anesthetize using the same predetermined method, The depth of anesthesia will controll and keep between 40 and 60(range of surgical anesthesia) by recording the Bispectral index. If any deviation will note (BIS>60 or BIS<40) & by increasing or decreasing dose of propofol the level of anesthesia will correct to reach the determined range.Finally,during&after termination of the surgery, the results for the length of operation, the detailed BIS number recordings, the total administered dose of propofol ,the length of anesthesia, the patients, Recovery time, and Intraoperative bleeding will record.

Category
Treatment - Drugs

2

Description

In first Control(placebo) group(non addicted)& second Control(placebo) group(addicted) tab Vit. C(2mg/kg)90min before operation will prescribe and then The patients will anesthetize using the same predetermined method, The depth of anesthesia will controll and keep between 40 and 60(range of surgical anesthesia) by recording the Bispectral index. If any deviation will note (BIS>60 or BIS<40) & by increasing or decreasing dose of propofol the level of anesthesia will correct to reach the determined range.Finally,during&after termination of the surgery, the results for the length of operation, the detailed BIS number recordings, the total administered dose of propofol ,the length of anesthesia, the patients, Recovery time, and Intraoperative bleeding will record.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Dr. Alireza Mirkheshti

Street address

Madani street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Anesthesia Research Center, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ali Dabbagh

Street address

Velenjak

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Anesthesia Research Center, Shahid Beheshti 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

Anesthesia departement , Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Davood Ommi

Position

MD, Anesthesiology Resident

Other areas of specialty/work

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Full name of responsible person

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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