

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The impact of adding clonidine in total sedative agents use in mechanically ventilated patients in the intensive care unit: A prospective, randomized, double blind study

Protocol summary

Summary

The purpose of this study is evaluation of sedative effects of clonidine and it's role in decreasing total sedative agents use including opioids, midazolam, other benzodiazepines, and propofol in critically ill mechanically ventilated patients. In this randomized, double blinded, 2-armed parallel group clinical trial, 40 patients will be recruited from intensive care unit, Imam Hussein hospital, SBMU, Tehran, Iran. After randomization the subjects in group A will receive clonidine 0.1mg TDS at day 1 and then 0.2mg TDS for 7 days. Subjects in group B will receive placebo. Primary outcome measure is change in total sedative agents use including opioids, midazolam, other benzodiazepines, and propofol in two groups. Secondary outcome measures include: 1-duration of mechanical ventilation 2- length of stay in ICU 3- serum level of clonidine in critically ill patients 3 and 7 after oral days administration of clonidine

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102910178N3**

Registration date: **2012-11-14, 1391/08/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-14, 1391/08/24

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-05-21, 1392/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of adding clonidine in total sedative agents use in mechanically ventilated patients in the intensive care unit: A prospective, randomized, double blind study

Public title

Effect of clonidine in total sedative agents use in the intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients on mechanical ventilation

Exclusion criteria: mechanical ventilation less than 3 days; sepsis; volume depletion; second or third degree atrioventricular node block; GFR < 15 ml/min; hepatic failure (Child Pough score: severe); GCS < 8; use of clonidine during past month

Age
From **18 years** old to **149 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

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

Street address

Velenjak Street, Shahid Chamran High Way

City

Tehran

Postal code

Approval date

2012-07-31, 1391/05/10

Ethics committee reference number

1391-1-94-10124

Health conditions studied

1

Description of health condition studied

Mechanically ventilated patients in the intensive care unit

ICD-10 code

J00-J99

ICD-10 code description

Diseases of the respiratory system

Primary outcomes

1

Description

Total sedative agents use including opioids, midazolam,

other benzodiazepines and propofol

Timepoint

Daily

Method of measurement

Total daily dose

Secondary outcomes

1

Description

clonidine blood level

Timepoint

day 4 and 7

Method of measurement

ELisa kit

2

Description

Duration of mechanical ventilation

Timepoint

Daily

Method of measurement

Daily

3

Description

Duration of ICU LOS

Timepoint

Daily

Method of measurement

Daily

Intervention groups

1

Description

clonidine 0.1mg TDS orally day 1 then 0.2mg TDS orally for total of 7 days

Category

Treatment - Drugs

2

Description

Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

ICU, Imam Hussein Hospital

Full name of responsible person

Mohammad Sistanizad

Street address

Shahid Madani Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
shahid beheshti university of medical sciences
Full name of responsible person
Tahereh shams
Street address
Velenjak street, shahid chamran High Way
City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

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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