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 opiods, 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 opiods, 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
Country
Iran (Islamic Republic of)
Phone
+98 21 8820 0087
Email address
sistanizadm@sbmu.ac.ir

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 opiods, 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

City

Tehran

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

Name of organization / entity

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Sistanizad

Position

Assistant Professor / Clinical Pharmacy Specialist

Other areas of specialty/work

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway

City

Tehran

Postal code

Phone

+98 21 8820 0087

Fax

Email

sistanizadm@sbmu.ac,ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Majid Mokkhtari

Position

Assistant Professor / FCCP

Other areas of specialty/work

Street address

ICU, Imam Hussein Hospital, Shahid Madani Street

City

Tehran

Postal code

Phone

+98 21 7755 8081

Fax

Email

majidmokh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway

Full name of responsible person

Maryam Farasatinasab

Position

Clinical Pharmacist

Other areas of specialty/work

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Niaesh Highway

City

Tehran

Postal code

Phone

00

Fax

Email

mary_farasati@yahoo.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