Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparative study of the combination of dexmedetomidine-propofol, dexmedetomidine and propofol for sedation during mechanical ventilation in patients hospitalized in the intensive care unit

Protocol summary

Study aim
Comparative determination of the combination of dexmedetomidine-propofol, dexmedetomidine and propofol for sedation during mechanical ventilation in patients hospitalized in the intensive care unit

Design
Clinical trial, with parallel groups, three blinded, randomized, phase 3 on 90 patients, random allocation software was used for randomization

Settings and conduct
This study is a three-blind clinical and comparative study of patients who underwent mechanical ventilation and were admitted to the special care department of Al-Zahra (S) and Kashani Hospitals in Isfahan in 1402-1403. Patients who meet all the inclusion criteria were included in the study after obtaining informed consent. These patients are randomly divided into 3 groups

Participants/Inclusion and exclusion criteria
Study inclusion criteria: Age over 18 and under 70 Criteria for not entering the study: Patients with serious mental disorders and dementia Patients with contraindications to dexmedetomidine or propofol Patients with allergies to any of the drugs Patients who are unable to continue the research process for any reason. People with acute infectious diseases or severe underlying diseases

Intervention groups
An initial loading dose of dexmedetomidine or propofol was given to rapidly achieve stable plasma concentrations. In the first group, the loading dose of dexmedetomidine was 1 µg kg–1 h–1 within 10 minutes and then the infusion 0.1 µg kg–1h–1 and in the second group propofol (1%) loading dose 1 mg kg–1 within 10 minutes and then 1 mg kg–1 kg–1 h–1 infusion in the third group dexmedetomidine loading dose 0.5 µg kg–1 h-1 with the addition of propofol 0.5 mg kg-1 and then dexmedetomidine 0.05 µg kg-1h-1 with the addition of 0.5mg propofol kg-1kg-1h-1

Main outcome variables
Average dose of propofol consumed, average dose of dexmedetomidine consumed, average duration of mechanical respiration, blood pressure,heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N54**
Registration date: **2023-10-17, 1402/07/25**
Registration timing: **prospective**

Last update: **2023-10-17, 1402/07/25**
Update count: **0**

Registration date
2023-10-17, 1402/07/25

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the combination of dexmedetomidine-propofol, dexmedetomidine and propofol for sedation during mechanical ventilation in patients hospitalized in the intensive care unit

Public title

study of the combination of dexmedetomidine-propofol, dexmedetomidine and propofol for sedation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years and under 70 mechanical ventilation hospitalized in the intensive care unit, Glasgow coma number is less than 9.

Exclusion criteria:

Patients with contraindications to dexmedetomidine and propofol Patients with serious mental disorders and dementia People with acute infectious diseases or severe underlying diseases including liver dysfunction, cardiovascular disorders including heart block, heart rate ≤ 60, heart failure with ejection fraction ≤ 30%, diabetes or severe blood pressure (120/180)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in a simple way. The samples are randomly placed in three intervention groups 1, 2 and 3 by means of random allocation software. Sampling continues until the samples in all three groups reach the set limit

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a three-way blind clinical trial, so that the patient is included in the study but does not know the type of intervention applied and is blind, the person who records the patient's symptoms is also different from the person who injects the medicine. And without knowing the type of medicine, he only records the patient's symptoms during the study and therefore is kept blind. The analysts who analyze the data collected during the study also do not know the type of intervention applied in each group and are blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Minimum ethics in the research of medical school of Isfahan University of Medical Sciences

Street address

Hear jerib

City

Esfahan

Province

Isfehan

Postal code

8174673461

Approval date

2023-10-14, 1402/07/22

Ethics committee reference number

IR.MUI.MED.REC.1402.261

Health conditions studied

1

Description of health condition studied

Need for sedation during mechanical ventilation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sedation rate of patients

Timepoint

At the base time (before the start of the intervention) and then every 24 hours

Method of measurement

The level of patient sedation will be evaluated using the Ramsay criterion, whose validity and reliability have been confirmed by a recent study

Secondary outcomes

1

Description
Mean arterial pressure
Timepoint
Baseline time (before the start of the intervention) then every 6 hours
Method of measurement
barometer

2

Description
Heart Rate
Timepoint
Baseline time (before the start of the intervention) then every 6 hours
Method of measurement
ECG

3

Description
Arterial blood oxygen saturation
Timepoint
Baseline time (before the start of the intervention) then every 6 hours
Method of measurement
pulse oximeter

4

Description
blood pressure
Timepoint
Baseline time (before the start of the intervention) then every 6 hours
Method of measurement
Barometer

Intervention groups

1

Description
Intervention group: In the first group, the loading dose of dexmedetomidine was 1 µg kg–1 h–1 within 10 minutes and then the infusion 0.1 µg kg–1h–1
Category
Treatment - Drugs

2

Description
Intervention group: In the second group, propofol (1%) loading dose of 1 mg kg-1 within 10 minutes and then infusion of 1 mg kg-1 kg-1h-1
Category
Treatment - Drugs

3

Description
Intervention group: In the second group, propofol (1%) loading dose of 1 mg kg-1 within 10 minutes and then infusion of 1 mg kg-1 kg-1h-1
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Behzad nazemoroaya
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available