

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 $\leq 30\%$, 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

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Hear jerib

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Isfahan

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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

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Recruitment center

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Sponsors / Funding sources

1

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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

Name of organization / entity
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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