

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Fentanyl-Magnesium sulfate and Fentanyl-Midazolam combination administration on hemodynamic status and sedation rate of patients undergoing mechanical ventilation in Intensive Care Unit (ICU)

Protocol summary

Study aim

Investigating the effect of Fentanyl-Magnesium sulfate and Fentanyl-Midazolam on hemodynamic status and sedation rate

Design

The clinical trial, with parallel groups, triple-blind, randomized, phase 2 on 40 patients. Random allocation software will be used for randomization.

Settings and conduct

This is a triple-blind randomized clinical trial conducted on 40 patients admitted to the ICU of Al-Zahra Hospital, Isfahan. After the approval of the ethics committee and obtaining consent, if the entry criteria exist, patients will be randomly assigned to the groups, the desired intervention will be applied, and the symptoms will be recorded. The researcher who records the patient's symptoms is different from the clinical caregiver who applies the intervention, the patient's guardians, and the data analysts also have no knowledge of the type of intervention. therefore, they are all blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18 to 75 years, admitted to the intensive care unit, requiring mechanical ventilation for at least 12 hours, and consent to enter the study. Non-entry inclusion: central nervous system disorder, use of neuromuscular blocking compounds, epidural anesthesia, history of allergy to the drugs used, tracheostomy patients, pregnant and lactating women

Intervention groups

Intervention group A: patients receive an initial dose of 1.5 µg/kg of Fentanyl and an initial dose of 0.3 mg/kg of Midazolam as a bolus upon entering the ICU, and continue to receive the same amount of Fentanyl and Midazolam as an infusion every hour. Intervention group B: patients receive an initial dose of 1.5 µg/kg of Fentanyl as a bolus upon entering the ICU, followed by

1.5 µg/kg of Fentanyl and 2 grams of Magnesium Sulfate as an intravenous infusion every hour for 6 hours.

Main outcome variables

Changes in hemodynamic status, degree of sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N44**

Registration date: **2022-09-08, 1401/06/17**

Registration timing: **prospective**

Last update: **2022-09-08, 1401/06/17**

Update count: **0**

Registration date

2022-09-08, 1401/06/17

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

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Fentanyl-Magnesium sulfate and Fentanyl-Midazolam combination administration on hemodynamic status and sedation rate of patients undergoing mechanical ventilation in Intensive Care Unit (ICU)

Public title

Investigating the effect of the combination of Fentanyl-Magnesium sulfate and Fentanyl-Midazolam on hemodynamic status and sedation rate

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 75 years Bedridden in ICU Requires mechanical ventilation for at least 12 hours Consent to participate in the study

Exclusion criteria:

Central nervous system disorders Weight more than 120 kg Use of neuromuscular blockers General or regional anesthesia allergy to the drugs used Tracheostomy patients pregnant and breastfeeding women

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by the simple method in which each patient will be assigned a code using a random number table (Random allocation software) and Patients fall into one of two groups depending on whether these codes are even or odd. This continues until the number of patients in both groups reaches the required number.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a Triple-blind clinical trial; In this way, the researcher who records the patient's symptoms is different from the nurse who injects the drug and does not know the type of drug and is blind. The analysts who

analyze the data collected during the study also know the type of intervention. It does not exist in any group and is blind. Even though the patient's guardians are included in the study, they do not know the type of intervention and are blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib

City

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Province

Isfahan

Postal code

8174673461

Approval date

2022-05-20, 1401/02/30

Ethics committee reference number

IR.MUI.MED.REC.1401.075

Health conditions studied**1****Description of health condition studied**

Mechanical ventilation in the ICU

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The amount of sedation

Timepoint

Every hour to 24 hours

Method of measurement

Richmond Anxiety-Sedation Scale

2**Description**

Pain amount

Timepoint

Every hour to 24 hours

Method of measurement

Visual Analogue Scale

3**Description**

Blood Pressure

Timepoint

Every hour to 24 hours

Method of measurement

Sphygmomanometer

4**Description**

Heart Rate

Timepoint

Every hour to 24 hours

Method of measurement

Electrocardiogram

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group A: In this group, patients are examined in terms of disease severity and hemodynamic status upon entering the ICU, and their vital signs are recorded. Then 1.5 µg/kg initial dose of Fentanyl manufactured by Caspian Company and 0.3 mg/kg initial dose of Midazolam manufactured by Aburihan Company will be received as a bolus, and then they will receive the same amount of Fentanyl and Midazolam as an infusion every hour. The condition and symptoms of the patient are checked and recorded for up to 24 hours.

Category

Diagnosis

2**Description**

Intervention group B: In this group, patients are examined for the severity of the disease and hemodynamic status upon entering the ICU, and their vital signs are recorded. Then they receive an initial dose of 1.5 µg/kg of Fentanyl as a bolus and continue every hour. They receive 1.5 µg/kg of Fentanyl and 2 g of Magnesium Sulfate as intravenous infusion for 6 hours. The condition and symptoms of the patient are checked and recorded up to 24 hours.

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

Behzad Nazem Roaya

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Alzahra hospital, Softe blvd.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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
Esfahan University of Medical Sciences

Full name of responsible person
Sahar Meraatian

Position
Anesthesiology resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Professor assistant of Anesthesia and Intensive care intensive care

Latest degree
Specialist

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Person responsible for updating data

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