

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects sedation induced by fentanyl and remifentanyl in patients under mechanical ventilation in the intensive care unit

Protocol summary

Summary

Objectives: Mechanical ventilation and inducing controlled sedation and analgesia with proper depth of anesthesia and the least complications is one the treatment goals in patients who are admitted to the intensive care unit. Because the cause of hospitalization and the physical condition of these patients is highly variable and often unstable, therefore recommending a unique standard model has not been achieved for all of them. In this study the level and also the side effects of fentanyl and remifentanyl is compared. Design: Block randomization, without placebo, double center, trial phase 2, including 70 patients under mechanical ventilation. Participants including major eligibility criteria: All patients who are supposed to be under mechanical ventilation. Intervention: Remifentanyl, 3 µg/kg/hr, intravenous injection. Fentanyl, 1 µg/kg/hr, intravenous injection. Main outcome measures: Sedation level, duration of ventilation, blood pressure, heart rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012311398N8**

Registration date: **2015-02-06, 1393/11/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-06, 1393/11/17

Registrant information

Name

Mohammad Reza Ghodrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects sedation induced by fentanyl and remifentanyl in patients under mechanical ventilation in the intensive care unit

Public title

Comparison of the effects of anesthesia level of fentanyl and remifentanyl in intensive care unit patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years old; Neurosurgical intensive care unit patients who need mechanical ventilation in the first 24 hours before or after neurosurgery; Stable hemodynamic. Exclusion criteria: Neuromuscular diseases; History of taking neuromuscular blocker medications; Pregnancy; Opium addiction.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Headquarters building, 5th floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

93 3348 /105/5

Health conditions studied

1

Description of health condition studied

Mechanical ventilation

ICD-10 code

Z51.8

ICD-10 code description

Other specified medical care

Primary outcomes

1

Description

Sedation level

Timepoint

Every 2 hours in the first 6 hours and then every 6 hours since the first 24 hours

Method of measurement

Sedation scale

2

Description

Ventilation duration

Timepoint

Since ventilation to the time removing the device from the patient

Method of measurement

Chronometer

3

Description

Blood pressure

Timepoint

Every 2 hours in the first 6 hours and then every 6 hours since the first 24 hours

Method of measurement

Sphygmometer

4

Description

Heart rate

Timepoint

Every 2 hours in the first 6 hours and then every 6 hours since the first 24 hours

Method of measurement

Monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Remifentanyl, 3 µg/kg/hr, intravenous injection, made in Normon company, Spainia.

Category

Treatment - Drugs

2

Description

Fentanyl, 1 µg/kg/hr, intravenous injection, made in Aboo-Reyhan company, Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool-e Akram hospital

Full name of responsible person

Fatemeh Sadat Mazhari

Street address

Rasool-e Akram hospital, Niyayesh street, Satarkhan street, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Fatemeh Sadat Mazhari

Street address

Firoozgar hospital, Firoozgar Hospital, Beh-afarin St. Karim Khan Av.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Headquarters building, 2nd floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences, Vice Chancellor for Research

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

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Mazhari

Position

Anesthesiology assistant

Other areas of specialty/work**Street address**

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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