

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The impact of sedation protocol using Richmond Agitation-Sedation Scale (RASS) on some clinical outcomes of mechanically ventilated patients in the Intensive Care Unit (ICU): A Clinical Trial

Protocol summary

Summary

Study objective: To Determine the effect of sedation protocol using Richmond Agitation-Sedation Scale (RASS) on clinical outcomes of mechanically ventilated patients in Intensive Care Unit (ICU) Study design: Single blind Randomized Clinical Trial, including intervention and control groups, single center, phase 1 trial. Study method: a) Sample size: A total of 90 patients will randomly divided into two groups of intervention and control group (N= 45 for each group). b) Randomization: All the eligible patients will be included in the study from Feb 2017 to May 2017 (The Poisson simple random sampling). The first five patients will be allocated to the intervention (head) or control (tail) group, and the second five patients will be allocated to the other group (tails) using tossing a coin. c) Intervention: In this study, the control group will receive the routine treatment and sedation according to the patients' physiological reactions and nurses' clinical judgment to control pain. In the intervention group the control of pain and sedation will be managed using a researcher-made designed protocol. In the proposed protocol, the sedation level of patients will be assessed and recorded using RASS Scale each hour, at the same time of assessment of patients' vital signs by nurses. No particular intervention will be needed if the score is less than -2. If the patient's Richmond score is between 1 and -1, sedation drugs will be infused just before invasive procedures. However, the patient will receive the appropriate nursing interventions (non-drug interventions) such as repositioning, reducing the endotracheal tube pressure on mouth or nose, reducing environmental noise, etc. if their sedation level score is more than +2. If the patients are sedated, the sedation level will be checked hourly; otherwise, the RASS Scale will be applied and the sedative drugs will be administered according to the patient's medication order. d) Intervention duration: The scoring of patients'

sedation level will be assessed using RASS scale, and the appropriate interventions (drug and non-drug) will be done hourly during the mechanical ventilation (maximum of 10 days) throughout the day (24 hours). e) Outcomes under study: Ventilation duration, ICU stay duration, the final outcomes including transferring from the ICU and death.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010831824N1**

Registration date: **2017-11-06, 1396/08/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-06, 1396/08/15

Registrant information

Name

Zahra Taran

Name of organization / entity

Zanjan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of sedation protocol using Richmond Agitation-Sedation Scale (RASS) on some clinical outcomes of mechanically ventilated patients in the Intensive Care Unit (ICU): A Clinical Trial

Public title

The impact of sedation protocol on some clinical outcomes of mechanically ventilated patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Intubated patient; need to have mechanical ventilation; no addiction (according to patient records and information from patient attendants); Range of age: between 15 and 65; RASS score higher than -3 scores; and GCS score between 5 and 13. Exclusion criteria: consciousness and extubation during first 24 hours; changing prescribed medicine by the physician; stopping the sedative prescribed medicine; transferring to the operating room; dramatical decrease in the level of patient's consciousness; continuous sedative infusion.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization: All the eligible patients will be included in the study from Feb 2017 to May 2017 (The Poisson simple random sampling). The first five patients will be allocated to the intervention (head) or control (tail) group, and the second five patients will be allocated to the other group (tails) using tossing a coin.

Secondary Ids

empty

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

Ethics Committee of Zanjan University of Medical Sciences

Street address

Vice chancellor for research Zanjan University of Medical Sciences, Azadi Square, Zanjan, Iran

City

Zanjan

Postal code

45156-13191

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

ZUMS.REC.1395.215

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

Sedation

ICD-10 code

Z53, Z53.0

ICD-10 code description

Persons encountering health services for specific procedures, not carried out

Primary outcomes**1****Description**

Duration of mechanical ventilation

Timepoint

Daily

Method of measurement

Counting hospitalization days

Secondary outcomes**1****Description**

Death

Timepoint

Daily

Method of measurement

Patient's records

2**Description**

Duration of hospitalization at Intensive Care Unit

Timepoint

At the end of hospitalization at Intensive Care Unit

Method of measurement

Counting the hospitalization days

3**Description**

Transferring from the ICU to the ward

Timepoint

Daily

Method of measurement

Patient's records

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

In the proposed protocol, the sedation level of patients will be assessed and recorded using RASS Scale each hour, at the same time of assessment of patients' vital signs by nurses. No particular intervention will be needed if the score is less than -2. If the patient's Richmond score is between 1 and -1, sedation drugs will be infused just before invasive procedures. However, the patient will receive the appropriate nursing interventions (non-drug interventions) such as repositioning, reducing the endotracheal tube pressure on mouth or nose, reducing environmental noise, etc. if their sedation level score is more than +2. If the patients are sedated, the sedation level will be checked hourly; otherwise, the RASS Scale will be applied and the sedative drugs will be administered according to the patient's medication order.

Category

Treatment - Drugs

2**Description**

The control group will receive the routine treatment and sedation according to the patients' physiological reactions and nurses' clinical judgment to control pain.

Category

Treatment - Drugs

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

Zanjan Ayatollah Mousavi hospital

Full name of responsible person

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

Vice chancellor for research Zanjan University of Medical Sciences

Full name of responsible person

Miss Vargaee

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Grant name**Grant code / Reference number**

A-11-147-6

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research Zanjan 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**

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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

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical sciences

Full name of responsible person

Zahra Taran