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

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Zahra Taran
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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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Zanjan

Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Miss Vargaee
Street address
Zanjan University of Medical Sciences, Azadi square, Zanjan
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Zanjan
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

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Person responsible for scientific inquiries

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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