

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of using Richmond Sedation-Agitation Scale on the length of stay and mechanical ventilation in ICU patients

Protocol summary

Summary

Objectives; The aim of this study is to evaluate the effects of using Richmond sedation-agitation protocol on the length of hospitalization and mechanical ventilation dependency in ICU patients. Design; randomized clinical trial study Setting and conduct; patients hospitalized in hospital affiliated of Ahvaz Jundishapur University will be chosen according to inclusion criteria. and then the samples will be allocated randomly into two groups of intervention and control by the stratified blocking method. Major Inclusion and Exclusion criteria; The patient suffers from the brain trauma and was under the ventilator machine, the lack of family consent for the patient involve in the study. Intervention; As soon as a patient gets anxious and agitated and every 6 hours by using Richmond sedation-agitation protocol, their level of sedation and agitation in the intervention group will be measured by the researcher and then the final score will be informed to the anesthesia specialist of the ward, he then will order or change the type and dosage of the sedative drugs for the patient based on the score obtained and on the basis of Richmond protocol, if necessary. The control group will not take any intervention and receive routine care of the ward only, Main outcome measures; Length of hospitalization in ICU, mechanical ventilation dependency.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610129469N2**

Registration date: **2017-01-22, 1395/11/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-22, 1395/11/03

Registrant information

Name

Mohammad Adineh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 1620 0140

Email address

mohadineh@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of using Richmond Sedation-Agitation Scale on the length of stay and mechanical ventilation in ICU patients

Public title

The effects of using Richmond Sedation, Agitation Scale on the length of stay and mechanical ventilation in ICU patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patient with brain truma is intubated and under ventilator; GCS score of ≥ 4 ; Not using neuromuscular blocker drugs ; The patient's age is between 16 -65 years old; Patient not be hyper active delirium with the physician diagnosis; Patient has no contraindications to the use of midazolam, lorazepam and propofol drugs. Exclusion criteria: Lack of family consent for the patient participation in the study; The patient transferred to other centers during the study; Patient takes neuromuscular blocker drugs during the study; Patient becomes hyperactive delirium during the study; Making a contraindication for using one of the midazolam, lorazepam and propofol drugs by the patient during the study; Patient agitation is not relieved by Richmond protocol during the study.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **103**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ethics Committee, Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences.

City

Ahvaz

Postal code

Approval date

2016-07-23, 1395/05/02

Ethics committee reference number

REC.1395.386

Health conditions studied

1

Description of health condition studied

Head trauma

ICD-10 code

S06.3, S06

ICD-10 code description

Focal brain injury, Epidural hemorrhage, Traumatic subdural hemorrhage, Traumatic subarachnoid hemorrhage, Intracranial injury with prolonged coma, Other intracranial injuries, Intracranial injury, unspecified

Primary outcomes

1

Description

Hospitalization period in ICU

Timepoint

Number of days hospitalized

Method of measurement

Checklist

Secondary outcomes

1

Description

Dependence on mechanical ventilation period

Timepoint

Number of days dependence on mechanical ventilation

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group: As soon as a patient gets anxious and agitated and every 6 hours by using Richmond sedation-agitation protocol, their level of sedation and agitation during monitoring under ventilator will be measured by the researcher and then the final score will be informed to the anesthesia specialist of the ward. Then, he will order or change the type and dosage of the sedative drugs for the patient based on the scores , if necessary.

Category

Treatment - Other

2

Description

Control group: non-use of Richmond protocol, receive routine care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam khomini hospital

Full name of responsible person

Mohammad Adineh

Street address

Naderi st, Emeam hospital, Ahvaz

City

Ahvaz

Golestan st, School of Nursing and Midwifery, Ahvaz
Jundishapur University of Medical Sciences, Ahvaz.

City

Ahvaz

Postal code

Phone

+98 61 3554 2036

Fax

Email

mohadineh@gmail.com; adineh-m@ajums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Behzad Makmalzadeh

Street address

Golestan st, Vice chancellor for research, Ahvaz
Jundishapur University of Medical Sciences, Ahvaz

City

Ahvaz

Grant name

119

Grant code / Reference number

3849

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur
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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Adineh

Position

Instructor of Nursing

Other areas of specialty/work

Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Adineh

Position

Master of critical nursing sciences

Other areas of specialty/work

Street address

Golestan st, School of Nursing and Midwifery, Ahvaz
Jundishapur University of Medical Sciences, Ahvaz.

City

Ahvaz

Postal code

Phone

+98 61 3554 2036

Fax

Email

mohadineh@gmail.com; adineh-m@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Adineh

Position

master of critical nursing

Other areas of specialty/work

Street address

Golestan st, School of Nursing and Midwifery, Ahvaz
Jundishapur University of Medical Sciences, Ahvaz.

City

Ahvaz

Postal code

Phone

+98 61 3554 2036

Fax

Email

mohadineh@gmail.com; adineh-m@ajums.ac.ir

Web page address

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