Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Effectiveness of Range of Motion Exercise on Prevention of Delirium in Intensive Care Units

Protocol summary

Study aim
Evaluation of Effectiveness of Range of Motion Exercise on Prevention of Delirium in Intensive Care

Design
Randomized clinical trial with parallel control group

Settings and conduct
The research environment in this study includes the ICU of Imam Khomeini Hospital affiliated to Ahvaz Jundishapur University of Medical Sciences and the research population including all patients admitted to ICU in this hospital.168 patients hospitalized in this unit were selected based on inclusion criteria and randomly assigned into intervention and control groups.The intervention group will be treated with a daily range of motion exercise program. There will be no intervention in the control group. Finally, the incidence of delirium in the two groups will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years; Stay at ICU for at least 24 hours. Exclusion criteria: Patients with visual impairment; Lower limb amputation; Previous history of cognitive impairment (dementia and psychosis); Drug poisoning; Increased intracranial pressure; Myocardial ischemia and arrhythmia; Hyperthermia; Admission to ICU after cardiac arrest; Patients with a Richmond score of 4- or 5-.

Intervention groups
1. The intervention group will undergo a range of motion exercises after daily evaluation. All patients in the intervention group performed exercises of the range of motion until discharge and 2 times a day, and each movement was performed 10 times in 30 second in the full range of upper and lower extremities and in a fully controlled position.These exercises will be performed on the wrists, elbows and shoulders in the upper extremities, and the ankle and knee and thigh joints in the lower extremities. 2. In the control group, no intervention is performed and care will be taken in accordance with the ICU routine.

Main outcome variables
Delirium

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180114038362N1**
Registration date: **2018-02-13, 1396/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-13, 1396/11/24**
Update count: **0**

Registration date
2018-02-13, 1396/11/24

Registrant information
Name
Azimeh Farzammanesh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 4224 5277
Email address
azimeh.farzammanesh@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2018-06-20, 1397/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Range of Motion Exercise on Prevention of Delirium in Intensive Care Units

Public title
Prevention of Delirium in Intensive Care Units
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Admitted in the ICU for at least 24 hours
Exclusion criteria:
Patients with visual impairment Patients with lower limb amputation Patients with previous history of cognitive impairment (dementia and psychosis) Patients with drug poisoning Patients with increased intracranial pressure Patients with myocardial ischemia and arrhythmia Patients with hyperthermia Admission to ICU after cardiac arrest Patients with a Richmond score of 4- or 5-
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **168**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with inclusion criteria based on random numbers table are assigned randomly in two groups of intervention and control.
Blinding (investigator's opinion)
Not 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 Jundishapur Ahvaz University of Medical Sciences
Street address
Golestan Blvd, Golestan, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2017-12-16, 1396/09/25
Ethics committee reference number
IR.AJUMS.REC.1396.709

Health conditions studied

1

Description of health condition studied
Delirium
ICD-10 code
F05
ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
Delirium score based on Intensive Care Delirium Screening Checklist
Timepoint
Evaluation of delirium level in 1, 2 and 3 days after admission
Method of measurement
Intensive Care Delirium Screening Checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will undergo a range of motion exercises after daily evaluation. All patients in the intervention group performed exercises of the range of motion until discharge and 2 times a day, and each movement was performed 10 times in 30 second in the full range of upper and lower extremities and in a fully controlled position.These exercises will be performed on the wrists, elbows and shoulders in the upper extremities, and the ankle and knee and thigh joints in the lower extremities.
Category
Prevention

2

Description
Control group: In the control group, no intervention is performed and care will be taken in accordance with the ICU routine.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini hospital
Full name of responsible person
Azimeh Farzammanesh
Street address
24 Shahid Ahvazian Ave
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 21 3292 3985
Email
azimeh.farzammanesh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Golestan Blvd, Golestan, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8070
Email
Badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Azimeh Farzammanesh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
Golestan Blvd, Golestan, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8070
Email
azimeh.farzammanesh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Azimeh Farzammanesh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
Golestan Blvd, Golestan, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8070
Email
azimeh.farzammanesh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person

Azimeh Farzammanesh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
Golestan Blvd, Golestan, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8070
Email
azimeh.farzammanesh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
اطلاعات بیشتری وجود ندارد
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available