

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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

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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

Type of organization providing the funding

Academic

Recruitment centers1**Recruitment center****Name of recruitment center**

Emam Khomeini hospital

Full name of responsible person

Azimeh Farzammanesh

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24 Shahid Ahvazian Ave

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Golestan Blvd, Golestan, Ahvaz

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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**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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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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