

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of nursing interventions and scheduled appointments versus control group on prevention of delirium in patients hospitalized in intensive care unit: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of nursing interventions and scheduled appointments versus control group on prevention of delirium in patients hospitalized in intensive care unit

Design

This is a randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the cluster randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Beheshti Hospital in Hamadan city on 96 eligible patients hospitalized in intensive care unit. The patients will be randomly assigned to the intervention and control groups through the cluster randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 70 years Indication for hospitalization in the intensive care unit Exclusion criteria: Cognitive disease Alcohol and drug addiction Visual or auditory disorders Loss of consciousness Taking psychoactive drugs History of stroke or liver cirrhosis or kidney failure

Intervention groups

Intervention group 1: The routine care of the ward in addition to nursing interventions including installing clocks and calendars in front of patients to inform them of the place and time, using appropriate light during the day and night, listening to radio and music and encouraging patients to increase mobility, informing patients about time, place and recent events. Intervention group 2: Routine care of the ward in addition to the scheduled appointments including washing the mouth and combing the patients' hair and encouraging them to drink fluids, as well as touching the patients and talking to them about their daily events and

topics of interest. Control group: Only routine care of the ward

Main outcome variables

Primary outcome: Delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N460**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **prospective**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of nursing interventions and scheduled appointments versus control group on prevention of delirium in patients hospitalized in intensive care unit: a randomized clinical trial

Public title
Effect of nursing interventions and scheduled appointments versus control group on prevention of delirium in patients hospitalized in intensive care unit

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 70 years Indication for hospitalization in the intensive care unit
Exclusion criteria:
Cognitive disease Alcohol and drug addiction Visual or auditory disorders Loss of consciousness Taking psychoactive drugs History of stroke or liver cirrhosis or kidney failure

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are assigned to intervention and control groups using cluster randomization method. For this purpose, three wards are considered, two wards are assigned to the intervention groups and one ward is assigned to the control group. Then, with enrolment of each patient, one of the wards is randomly selected and accordingly the patient is assigned to the relevant ward and group.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.UMSHA.REC.1401.938

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

Timepoint

On the first, second and third days after the intervention

Method of measurement

Using the CAM-ICU tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The routine care of the ward in addition to nursing interventions including installing clocks and calendars in front of patients to inform them of the place and time, using appropriate light during the day and night, listening to radio and music and encouraging patients to increase mobility, informing patients about time, place and recent events.

Category

Treatment - Other

2

Description

Intervention group 2: Routine care of the ward in addition to the scheduled appointments including washing the mouth and combing the patients' hair and encouraging them to drink fluids, as well as touching the patients and talking to them about their daily events and topics of interest.

Category

Treatment - Other

3

Description

Control group: Only routine care of the ward

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital in Hamadan city

Full name of responsible person

Parvaneh Ghaderi

Street address

Beheshti Hospital, Eram Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

parvaneh.ghaderi7313@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Parvaneh Ghaderi

Position

Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

parvaneh.ghaderi7313@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Morteza Shamsiadeh

Position

Master of Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Hamadan University
of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

mortezashamsizadeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available