

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of nursing care on prevention of sensory overload stimulation in patients admitted to the intensive care unit

Protocol summary

Study aim

Determining the effect of nursing care on the prevention of complications of sensory stimulation in patients admitted to ICU.

Design

Randomized clinical trial will be performed on 88 patients admitted to the ICU.

Settings and conduct

This study will be preformed in Besat hospital intensive care unit. Patients and researchers will not be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients admitted to the intensive care unit; Patients aged 20-70 years Exclusion criteria: Patient death; Change in the treat process or transfer to another medical center

Intervention groups

The intervention will take place for 7 nights and from the second night of admission. In the intervention group for patients, the blindfold and earplugs are used from 10 am to 6 am at the same time and there will be no intervention in the control group and only routine care will be provided. For 7 days, daily, using the RASS scale of restlessness and using the CAM-ICU scale, the incidence of delirium by the researcher will be measured in the morning shift in both groups.

Main outcome variables

Delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N9**

Registration date: **2018-02-12, 1396/11/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-12, 1396/11/23**

Update count: **0**

Registration date

2018-02-12, 1396/11/23

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-31, 1396/10/10

Expected recruitment end date

2018-12-31, 1397/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of nursing care on prevention of sensory overload stimulation in patients admitted to the intensive care unit

Public title

Effect of nursing care on prevention of sensory overload

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patients admitted in intensive care unit aged 20 to 70

years dont have RASS score between -4 and -5

Exclusion criteria:
death change in treatment process or transport to another ward

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly, 88 patients are selected. Then, using random blocks, they will be divided equally in to 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 Hamedan University of Medical Sciences

Street address

Shahid Fahmida St., Hamedan University of Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR.UMSHA.REC.1396.621

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

Before and 7 days after intervention

Method of measurement

Questionnaire and checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention will take place for 7 nights and from the second night of admission. In the intervention group, the blindfold and earplugl are used for patients from 10am to 6am at the same time.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Gholam hosein falahinia

Street address

Shahid Fahmida St., Hamedan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Grant name

Grant code / Reference number

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

No

Title of funding source

Deputy of Research and Technology of 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

Gholam hosein falahinia

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

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