Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The effect of multifactorial intervention on prevention of delirium in ICU patients of hospital

Protocol summary

Study aim
Determining the effect of multifactorial intervention on the prevention of delirium in patients admitted to the intensive care unit of a hospital

Design
A one-phase blind control clinical trial،by sequentially available sampling will be performed on 100 patients admitted to the intensive care unit with consecutive available sampling

Settings and conduct
Participants are unaware of which group they will be in.With daily visits to the intensive care units of trauma, neurosurgery, neurology and internal medicine sampling will be done.First, the control group were completely selected and for the same conditions with the intervention group, each patient was evaluated for delirium for seven days in the morning and evening shifts (6 am and 6 pm).Then intervention group will selected.In both groups, patients will be examined for delirium before enterance to the study and will be excluded if delirium presents.Then, multifactorial intervention will be performed for the intervention group during the first seven days.

Participants/Inclusion and exclusion criteria
inclusion criteria:age>18-No delirium on arrival-new admit patients(less than 24 hour)-absence of cognitive impairement-absence of severe hearing and vision impairment-Organ health in the soles-GCS>9-Awareness or consent to participate in the study (patient or first class companion).Exclusion criteria:discharge, expiration or transfer earlier than 48 hours-Dissatisfaction of the patient or the patient's companion to continue participating in the study

Intervention groups
Interventions include interventions for earplugs and blindfolds, reorientation, setting a calendar and clock and reflexology massage based on the framework of correcting the sensory overload and depriviation and based on valid scientific texts and articles. Control group will receive routine ward care.

Main outcome variables
delirium incidence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201129049530N1**
Registration date: **2020-12-05, 1399/09/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-05, 1399/09/15**
Update count: **0**

Registration date
2020-12-05, 1399/09/15

Registrant information

Name
reyhaneh sadeghian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3213 3314

Email address
reyhaneh.sadeghian@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-05, 1399/09/15

Expected recruitment end date
2021-03-05, 1399/12/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multifactorial intervention on prevention of delirium in ICU patients of hospital

Public title

The effect of multifactorial intervention on prevention of delirium in ICU patients of hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

age>18 Absence of delirium at the beginning of the study less than 24 hours from hospitalization Absence of Cognitive impairment Absence of severe hearing and vision impairment Organ health in the soles of the feet Having the consent or knowledge to participate in the study (patient or first-degree companion) GCS>9

Exclusion criteria:

Discharge, death or transfer earlier than 48 hours The unwillingness of the patient or the patient's companion to continue participating in the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, an anesthesiologist evaluates patients for delirium to confirm the researcher's diagnosis, and the statistical analyzer is unaware of whether patients are assigned to a control or intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

This study is a quasi-experimental study of two groups: an intervention group that receives the mentioned multifactorial interventions and a control group to determine the effect of multifactorial interventions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan university of Medical Sciences

Street address

Kerman, at the beginning of Esteghlal Street, Electronic Signal Store

City

Kerman

Province

Kerman

Postal code

7617798836

Approval date

2020-10-11, 1399/07/20

Ethics committee reference number

IR.ZAUMS.REC.1399.345

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 incidence

Timepoint

twice a day, from enterance of patients to the study upto 7 days

Method of measurement

RASS(Richmond Agitation Sedation Scale), CAM-ICU(Confusion Assessment Method for ICU), ICDSC(Intensive Care Delirium Screening Checklist)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Multi-factor intervention for patients in the intervention group will be performed during the first seven days of hospitalization and in the morning (6:30) and evening (6:30). This intervention includes interventions to install earplugs and blindfolds, re-awareness, setting a calendar and clock for the patient

and reflexology massage based on the framework of correcting the reduction and increase of sensory stimuli and based on valid scientific texts and scientific articles.

Category

Prevention

2

Description

Control group: This group is evaluated for the onset of delirium with the same tools as the intervention group in the morning and evening (6 o'clock) and receives routine care.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam hospital of Zahedan

Full name of responsible person

Reyhaneh Sadeghian

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Zahedan - Dr. Hesabi Square - Medical Sciences university

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Noor Mohammad Bakhshani

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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

Zahedan medical university

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

Zahedan University of Medical Sciences

Full name of responsible person

Narjes khaton Sadeghi

Position

student, researcher

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Professor

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Ph.D.

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

no more information

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