Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effects of family members presence on the incidence of delirium in Patients who admitted in cardiac intensive care unit (CICU)

Protocol summary

Study aim
Determining the effects of family members presence on the incidence of delirium in patients who admitted in cardiac intensive care unit (CICU)

Design
Clinical trial with control group with parallel groups, without blindness, randomized

Settings and conduct
In this study, 100 patients with acute coronary syndrome admitted to the coronary Care Unit of Imam Hossein Hospital in Shahroud will be selected based on the criteria of the researcher and will be randomized in the intervention and control group

Participants/Inclusion and exclusion criteria
Age over 60 years, Ability to speak and understand Persian language, Not having a sedative drug for a long time, Lack of sleep disorders like sleep apnea, The availability of first-degree relatives of the patient (including the father, mother, sister, spouse and child of the patient)

Intervention groups
Intervention group: In the intervention group, the time of visiting the first-degree relatives of the patient will be increased from one hour per day to two hours per day (one hour evening and one hour in the early hours of the night). Control group: The control group will not receive intervention and will only receive routine care and care at the hospital and discharge time.

Main outcome variables
patient's delirium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100114003064N10**
Registration date: **2018-06-30, 1397/04/09**
Registration timing: **registered_while_recruiting**
Last update: **2018-06-30, 1397/04/09**
Update count: **0**

Registration date
2018-06-30, 1397/04/09

Registrant information

Name
Hossein Bagheri

Name of organization / entity
Shahroud University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date
2018-06-22, 1397/04/01

Actual recruitment end date
2018-12-21, 1397/09/30

Trial completion date
empty

Scientific title
Evaluating the effects of family members presence on the incidence of delirium in Patients who admitted in cardiac intensive care unit (CICU)

Public title
Family members presence and delirium of Patients in cardiac intensive care unit (CICU)

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Ability to speak and understand Persian language The availability of first-degree relatives of the patient (including the father, mother, sister, spouse and child of the patient)

Exclusion criteria:

Those who are health care workers Having sleep disorders like sleep apnea

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups by block of 4: A (family members' presence) and B (control group). The allocation will be done concealment. In this way, there will be 70 envelopes, each with A and B codes. The envelopes will be numbered. Individuals will be coded according to their entry into the study, and will be allocated an envelope for each patient to the 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 Shahroud University of Medical Sciences

Street address

Haft Tir Square

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2017-10-30, 1396/08/08

Ethics committee reference number

Ir.Shmu.rec.1396.111

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.9

ICD-10 code description

Delirium, unspecified

Primary outcomes

1

Description

Score of delirium incidence based on Neecham and RASS score

Timepoint

Assessment of patients' delirium in the admission as well as on the second, third and fourth days of admission

Method of measurement

Neecham and RASS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, the time of visiting the first-degree relatives of the patient will be increased from one hour per day to two hours per day (one hour evening and one hour in the early hours of the night).

Category

Prevention

2

Description

Control group: The control group will not receive intervention and will only receive routine care and care at the hospital and discharge time.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr. Hossein Bagheri

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28-meter Touhidi, Imam Khomeini Street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahroud 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
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Person responsible for updating data

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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
ÎThere is 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