

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Survey of effectiveness of a multifactorial intervention in prevent of delirium in hospitalized patients in the Intensive Care Unit Cardiac Surgery

Protocol summary

Summary

Target: survey of effectiveness of a multi factorial intervention in prevent of delirium in hospitalized patients in the Intensive Care Unit Cardiac Surgery. Inclusion criteria: Patient's satisfaction; 18 years and over; lack of understanding and underlying disease; lack of taking psychotropic medication; lack of alcoholism; being healthy vision and hearing or eliminating defects by using of eyeglasses or hearing aids; restlessness and lack of level -5 and -4 based on RASS. Exclusion criteria: dispensing with sick; transfer the patient to other ward or hospital; cardiopulmonary resuscitation and endotracheal intubation and dying of patient. By convenience sampling patient selected in control and intervention groups. In each group, 48 samples recruited. Research tools included: assessment scale of turbulence, quietness Richmond "RASS" To assess the level of restlessness and "Neecham" scale to evaluate the incidence of delirium. In the intervention group In addition to common care multifactorial intervention with three professional components were done. its component include The intervention included educating staff about delirium and sticking of delirium tutorial diagnosis and treatment posters, also put a clock and calendar display cases and dreams of light with adjustable light and increase the frequency of meetings to twice a day in the afternoon and early evening and providing eyeglasses and hearing aids for patients who have difficulty seeing or hearing And at the end Incidence of delirium in the two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011220645N1**
Registration date: **2015-07-22, 1394/04/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-22, 1394/04/31

Registrant information

Name

Reza Babae

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

rbabae@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Qazvin University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of effectiveness of a multifactorial intervention in prevent of delirium in hospitalized patients in the

Intensive Care Unit Cardiac Surgery

Public title

Survey of effectiveness of a multifactorial intervention in prevent of delirium in hospitalized patients in the Intensive Care Unit Cardiac Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patient's satisfaction and fellows to participate in the survey; age 18 years and over; lack of understanding and underlying disease such as dementia; lack of alcoholism; ability to communicate and understand the Persian language; being healthy vision and hearing or eliminating defects by using of eyeglasses or hearing aids; not having a constant infusion of sedatives; the availability of the patient's family; restlessness and lack of level -5 and -4 based on RASS; lack of taking psychotropic medication. Exclusion criteria: dispensing with sick; transfer the patient to a medical center or other center; start sedative drugs constant infusion; cardiopulmonary resuscitation and endotracheal intubation and died of patient.

Age

From **17 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard

City

Qazvin

Postal code

3419759811

Approval date

2015-01-11, 1393/10/21

Ethics committee reference number

d/20/9886

Health conditions studied

1

Description of health condition studied

Postoperative Delirium

ICD-10 code

F05.8

ICD-10 code description

Other delirium, Postoperative Delirium

Primary outcomes

1

Description

Delirium

Timepoint

every day until the fourth day after surgery in both groups performed

Method of measurement

Neecham & RASS

Secondary outcomes

empty

Intervention groups

1

Description

By convenience sampling patient selected in control and intervention groups. In each group, 48 samples recruited. Research tools included: assessment scale of turbulence, quietness Richmond "RASS" To assess the level of restlessness and "Neecham" scale to evaluate the incidence of delirium. In the intervention group In addition to common care multifactorial intervention with three professional component were done. its component include The intervention included educating staff about delirium and sticking of delirium tutorial diagnosis and treatment posters , also put a clock and calendar display cases and dreams of light with adjustable light and increase the frequency of meetings to twice a day in the afternoon and early evening and providing eyeglasses and hearing aids for patients who have difficulty seeing or hearing And at the end Incidence of delirium in the two groups will be compared.

Category

Prevention

2

Description

There was no intervention in the control group and only RASS and Neecham scale was used to assess delirium in the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-ali Hospital

Full name of responsible person

Reza Babaee Master student of intensive care nursing

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Zeinab Jourabchi

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Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Boulevard

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Grant name

د/11/ب

Grant code / Reference number

10165/6/28

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

Yes

Title of funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Reza Babaee

Position

Master student of intensive care nursing

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty