

# 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)

###### Phone

+98 28 3323 7267

###### 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

**City**

Qazvin

**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

**Street address**

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

**City**

Qazvin

**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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PhD, Assistant Professor

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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**Fax****Email**

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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*