

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### Effect of family - patient communication on the incidence of delirium in hospitalized patients

#### Protocol summary

##### Summary

**Objectives,** This study has been done with the purpose of assessing the effect of the relationship between the family and the patient on the incidence of delirium in hospitalized patients in cardiovascular surgery ICU.

**Design,** This study is a two groups and single-blind (for the questioner) clinical trial. Setting and conduct, Study has been conducted on 68 patients in the cardiac surgery ICU of Shahid Cchamran hospital affiliated to Isfahan University of Medical Science. Sampling was convenient sampling, and the subjects were allocated to two groups (n= 34 patients) based on random numbers table. Participants including major eligibility criteria, Inclusion criteria were age of 18-70 years, availability of immediate family members, absence of addiction to drugs, alcohol and cigarette smoking, absence of delirium, consciousness level disorder and mental diseases before surgery, absence of blindness and deafness, elective open heart surgery, no family history for surgery, and absence of intubation with a tracheal tube. In cases of patients' or their reluctance to continue participation, death or existence of post-surgery acute complications, the patients were excluded from the study. Intervention, The day after surgery, one of the family members in intervention group who had been received the education was allowed to visit the patient in the morning shift. In the control group, subjects received routine care. Two groups were assessed for delirium ,three times, with use of RASS and CAM-ICU scale. Main outcome measures, Family - patient communication can reduce delirium.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201604107391N3**

Registration date: **2017-01-14, 1395/10/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-01-14, 1395/10/25

##### Registrant information

###### Name

Maryam Eghbali Babadi

###### Name of organization / entity

Isfahan University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7539

###### Email address

eghbali@nm.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-04-09, 1392/01/20

##### Expected recruitment end date

2013-08-11, 1392/05/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of family - patient communication on the incidence of delirium in hospitalized patients

##### Public title

Family - patient communication on the incidence of delirium

##### Purpose

Prevention

**Inclusion/Exclusion criteria**  
 Inclusion criteria: Availability of immediate family members; absence of addiction to drugs, alcohol and cigarette smoking; absence of delirium, consciousness level disorder and mental diseases before surgery; absence of blindness and deafness; elective open heart surgery; no past history for surgery; absence of intubation with a tracheal tube  
 Exclusion criteria: In cases of patients' or their reluctance to continue participation; death or existence of post-surgery acute complications

**Age**  
 From **18 years** old to **70 years** old

**Gender**  
 Both

**Phase**  
 2-3

**Groups that have been masked**  
*No information*

**Sample size**  
 Target sample size: **68**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
 Single 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 Isfahan University Of Medical Sciences

##### Street address

Isfahan University Of Medical Science, Hezar Jerib Avenue, Isfahan, Iran.

##### City

Isfahan

##### Postal code

009881746-73461

#### Approval date

2013-04-09, 1392/01/20

#### Ethics committee reference number

ir.mui.rec.1392.3.010

## Health condids studied

### 1

#### Description of health condition studied

Delirium

#### ICD-10 code

F05.9

#### ICD-10 code description

Delirium, unspecified

## Primary outcomes

### 1

#### Description

Delirium

#### Timepoint

Three times (before intervention, and twice in the morning and evening after the intervention)

#### Method of measurement

RASS and CAM-ICU scale

## Secondary outcomes

### 1

#### Description

Demographic data of Patients and family member

#### Timepoint

Once before the intervention

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Researcher held a two- hour class for the families to familiarize them with the goal, signs, causes, prevention methods of delirium and communicational methods and distributed pamphlets among them. These materials were reviewed before each visit with the family members. To administrate the intervention, from the day after surgery, when the patient was separated from ventilation device and was able to communicate, after making coordination with ICU staff and at a certain time of morning shift (once a day), a family member in study group(selected by the patient and undergone necessary education) was permitted to attend by the patient for 30-40 minutes and communicated with him/ her, based on the already received education after wearing a disposable gown, shoes cover, a mask and disinfection of the hands with an anti- bacterial spray.

#### Category

Prevention

### 2

#### Description

Control group:For the patients in control group, no special visit was scheduled and the family visited their

patients based on hospital regulations although their visits were recorded.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Chamran Hospital

**Full name of responsible person**

Maryam Eghbali Babadi

**Street address**

Shahid Chamran Hospital , Bridge Bozorgmehr, Third Moshtagh, Isfahan, Iran.

**City**

Isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research,Isfahan University Of Medical Sciences

**Full name of responsible person**

Dr Payman Adibi

**Street address**

Isfahan University O Medical Science, Hezar Jerib Avenue, Isfahan, Iran.

**City**

Isfahan

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice Chancellor for research,Isfahan 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**

Isfahan University Of Medical Sciences

**Full name of responsible person**

Maryam Eghbali Babadi

**Position**

Faculty Member

**Other areas of specialty/work**

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## 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*