Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 conditions 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

Street address

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

City

Isfahan

Postal code

Phone

+98 31 3792 2940

Fax

Email

eghbali@nm.mui.ac.ir

Web page address

Person responsible for scientific 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

Street address

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

City

Isfahan

Postal code

Phone

+98 31 3792 2940

Fax

Email

eghbali@nm.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan Univercity Of Medical Science

Full name of responsible person

Maryam Eghbali Babadi

Position

Faculty Member

Other areas of specialty/work

Street address

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

City

Isfahan

Postal code

Phone

+98 31 3673 5885

Fax

Email

eghbali@nm.mui.ac.ir

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