Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of orientation tour on post-operative delirium and anxiety of patients with open heart surgery

Protocol summary

Summary

The main objective of this study is to determine the effect of orientation tour in ICU on patients' delirium and anxiety incidences after open heart surgery. The research society includes all patients undergoing open heart surgery who will hospitalize in ICU after surgery. The samples of this research will be selected in terms of entry criteria including age, all patients who candidate for non-emergency open heart surgery and exit criteria including to refuse to continue participating in the study. The samples will be put in either the control group or in the test group by using simple random allocation method with 42 per group. To do this, both groups receive the unit routine education and intervention group, in addition to the unit routine education, receives orientation tour intervention which will be held in the form of 30-40-minute tour and they will be orientated with the unit environment, tools and equipment through simulation. In this research, the anxieties of the test and control groups will be measured by Spielbeger anxiety questionnaire at the night before the surgery, after extubating tracheal tube and during the discharge from ICU. Also, delirium will be evaluated by the researcher through ICDSC scale in the morning shift until the patients discharges from ICU and or for 5 days. According to this scale, the score 4 indicates delirium and the score higher than 4 (>4) indicates the incidence of delirium.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052734145N1**
Registration date: **2017-07-27, 1396/05/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of orientation tour on post-operative delirium and anxiety of patients with open heart surgery

Public title

Effect of orientation tour on the incidence delirium and anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Entry criteria: Age 30-65 years; All patients who candidate for non-emergency open heart surgery; Not with central nervous system disease; No consciousness level disorder; No use of the medicines effecting the psyche Exit criteria: To refuse to continue participating in the study; The need for re-surgery; Blood transfusion, more than 3 (>3) units

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

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 Iran University of Medical Sciences

Street address
Rasheed Yasemi Street, Higher than Mirdamad, Vali Asr Street, School of Nud Midwiferyrsing any

City
Tehran

Postal code
-

Approval date
2016-11-19, 1395/08/29

Ethics committee reference number
IR.lums.Rec95-9311449005

Health conditions studied

1

Description of health condition studied
Coronary and valvular heart surgery

ICD-10 code
I97.1

ICD-10 code description
Other functional disturbances following cardiac surgery

Primary outcomes

1

Description
Anxiety

Timepoint
After the intervention, post-extubation and before discharge

Method of measurement
Anxiety Inventory Spielberger

2

Description
Delirium

Timepoint
post orientation tour invention

Method of measurement
Check List of measuring delirium ICDSC

Secondary outcomes

1

Description
Increased length of stay in ICU

Timepoint
Post orientation tour inventio

Method of measurement
ICDSC

2

Description
Increase the duration of mechanical ventilation

Timepoint
Post Orientation tour Invention

Method of measurement
ICDSC

Intervention groups

1

Description
To do this, both groups receive the unit routine education and intervention group, in addition to the unit routine education, receives orientation tour intervention which will be held in the form of 30-40-minute tour and they will be orientated with the unit environment, tools and equipment through simulation

Category
Prevention

2

Description
In control group receive the unit routine education

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Center of Cardiology Fatemehzahra
Full name of responsible person
Ahmad Farajitabar
Street address
Center of Cardiology Fatemehzahra, Boulevard Artesh
City
Sari

2

Recruitment center
Name of recruitment center
Hospital North
Full name of responsible person
Ahmad Farajitabar
Street address
Hospital North,Boulevard Modarres
City
Amol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Iran University Of Medical Science
Full name of responsible person
Syed Ali Javad Mosavi
Street address
Between Sheikh Fadlallah and Chamran Expressway, Hemat Expressway, Iran University of Medical Sciences
City
Tehran
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, Iran University Of Medical Science
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
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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