Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of multifactorial intervention on prevention of delirium and duration of hospitalization in open heart surgery patients

Protocol summary

Summary

This study examined the effectiveness of a multifactorial intervention on delirium prevention and length of hospitalization in open heart surgery of Imam Khomeini hospital at 2010. In this semi-Experimental clinical trial, 195 recruited patients were divided in two intervention and control group. Inclusion criteria were who has 4 or 5 Level of consciousness with RASS scale. Exclusion criteria were emergency open heart surgery, history of psychoactive drugs or Addicted to alcohol, and postoperative complications. Intervention was staff education, environment changes and installation of poster on ward. Patients were assessed by CAM-ICU scale twice a day to identify incidence of delirium in two groups. Demographic, disease and sleep information Questionnaires completed by researcher on day before surgery. The incidence of delirium was recorded by flowchart. Delirium incidence and length of stay in hospital were compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101201599N8**
Registration date: **2011-06-15, 1390/03/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-15, 1390/03/25

Registrant information

Name

Mitra Zolfaghari

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

zolfaghm@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2010-08-20, 1389/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of multifactorial intervention on prevention of delirium and duration of hospitalization in open heart surgery patients

Public title

Effect of multifactorial intervention on prevention of delirium and duration of hospitalization

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: absense of underlying Cognitive diseases such as dementia, Level of consciousness 4- or 5 by RASS Score, Elective Heart surgery Exclusion criteria: Emergency open heart surgery, history of psychoactive drugs, addicted to alcohol, unwilling to participatation, postoperative complications (like bleeding, tamponade and ...).

Age
From **16 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Review Commiitee of Tehran University of Medical Sciences
Street address
Keshavarz BLD, Ghods street, Central building of Tehran University of Medical Sciences, 6th floor Tehran Tehran Iran, Islamic Republic Of
City
tehran
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
89-01-28-10263

Health conditions studied

1

Description of health condition studied
Delirium
ICD-10 code
F05
ICD-10 code description
Delirium, not induced by alcohol and other psychoactive substances

Primary outcomes

1

Description
delirium incidence
Timepoint
at the whole of hospitalizatin
Method of measurement
with CAM-ICU Scale, twice a day

Secondary outcomes

1

Description
lenght of stay
Timepoint
the wole of hospitalization from surgery day until discharge
Method of measurement
record on flowchart

Intervention groups

1

Description
educational dalirium workshop
Category
Prevention

2

Description
inistallation poster on open heart surgery ward
Category
Prevention

3

Description
enviornmental changes
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini(rh) Hospital
Full name of responsible person
Street address
Dr Gharib street
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Siences
Full name of responsible person
Khadije Bayat
Street address
Gavazang road, AyatolLah Mosavi Hospital
City
zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Siences
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Siences and Health Services
Full name of responsible person
Mitra Zolfaghari
Position
Instructor
Other areas of specialty/work
Street address
Tohid sq., East Nosrat st., Nursing & Midwifery School
City
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Fax
Email
zolfaghm@tums.ac.ir
Web page address

Person responsible for updating data

Contact

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