Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effects of preventive nursing measures on delirium incidence for patients with open heart surgery

Protocol summary

Summary

The purpose of this study is to evaluate the effect of preventive nursing measures on the delirium incidence of the patients with open heart surgery. This is a semi-experimental interventional study which will be carried out in 2015. Research sample includes 72 admitted patients at open heart surgery unit of Sari Fatima-Zahra Hospital. These patients have to be over 18 years with no delirium before surgery and its preoperative history and are subject to an elective open heart surgery. Exclusion criteria in this study are Impairment of consciousness, using psychological drugs, having a depressive disorder, recent use of opiate drug and alcohol, absolute blindness and deafness, emergency heart surgery, died during surgery or during investigation and Patients refuse to cooperate with preventive nursing measure during the study. All patients in the study are sampled based on availability and divided into two groups of control and intervention. At first, Researcher starts sampling without intervention from control group. After sampling from this group, Intervention will be initiated through preventive nursing measures and environmental changes. These interventions will be continued from the first day after surgery till the end of fifth day. Patients in both groups are evaluated in terms of delirium incidence based on NEECHAM every afternoon. Patient information questionnaire have to be completed by researcher one day before surgery. Delirium incidence cases can be recorded using a check list. A comparative study of delirium incidence in the two study groups are carried out.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015052622418N1**
Registration date: **2015-06-26, 1394/04/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-26, 1394/04/05

Registrant information

Name
Davod Adabifirozjayi
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, mazandaran University of Medical Sciences

Expected recruitment start date

2015-06-05, 1394/03/15

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of preventive nursing measures on delirium incidence for patients with open heart surgery

Public title
Prevention of delirium after open heart surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: no record of delirium before open heart surgery; Age of over 18 years; an elective open heart surgery Exclusion criteria: Impairment of consciousness; stroke; using psychological drugs; having a depressive disorder; Recent use of opiate drug and alcohol; absolute blindness and deafness; aphasia due to the inability to fill the questionnaire; having delirium on the first day after surgery; emergency heart surgery; having intubation more than 24 hours after surgery; died during surgery or during investigation; and Patients refuse to cooperate with preventive nursing measure during the study
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Not 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 Mazandaran University of Medical Sciences
Street address
Start of valiye asr highway, Imam Square, Sari, Mazandaran
City
Sari
Postal code
4736131167
Approval date
2015-05-24, 1394/03/03
Ethics committee reference number
Ir.Mazums.Rec.94،1454

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
The incidence of delirium
Timepoint
Patients of open heart surgery should be evaluated for delirium incidence during the day before surgery between 16 to 20 p.m. then, they have to be evaluated one day after surgery until the end of the fifth day of hospitalization once a day, at the same time. This evaluation is due to an increase of the delirium incidences in this period.
Method of measurement
The measure of the delirium incidence is based on Neecham questionnaire

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
After sampling in the control group, preventive measures are done by researcher in the intervention group from the first day after surgery till the end of the fifth day such as: Installation of clock and calendar at the room, informing time, place and the last event to the patient three times a day, using proper lighting during the day and night, providing glasses, hearing aids and dentures to the patients who already used these devices, Prevention from dehydration (drinking enough liquids in case of dehydration and no contraindications), Encouraging the patient to move out of bed and helping him/her to do personal activities in order to maintain his independence, Preparations for a proper sleep (not using coffee, tea and dairy products before sleep time, enough exercise during the day, Reducing or eliminating

unwanted extra noise around the bed and gentle massage on the back of the patient), preventing constipation (enough drinking, proper food diet with enough fiber and exercise during the day) not using physical limitations if possible, using local languages in the care of patients with diverse language and culture, using replaced oxygen to keep content of arterial oxygen above 95% and regular scheduled visit of the family and friends twice a day, each time for 30 minutes. The role of family and close friends at the patient bedside: (1) informing the patient about the place, time and recent events, providing the patient's favorite music or radio program or provide a cassette that recorded the voices of family members) 2(present the familiar objects in the room by their patients (photos, books, newspapers, pillows or soft pillows)

Category

Prevention

2

Description

The researcher selects control group patients among all eligible patients who participate in this study. The control group received the usual nursing care and haloperidol injection.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Fatima Zahra Hospital

Full name of responsible person

Davod Adabifirozjayi

Street address

Imamhoseyn Square, Sari, Mazandaran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of, mazandaran University of Medical Sciences

Full name of responsible person

Doctor Ahmadali Enayati

Street address

Moallem Square, Sari, Mazandaran

City

Sari

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 of, mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Davod Adabifirozjayi

Position

Master Student of Critical Care Nursing

Other areas of specialty/work

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-

Person responsible for scientific inquiries

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Position

Assistant Professor, scientific committee

Other areas of specialty/work

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Position

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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