Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Influence of a multifactor-adjusted intervention based on NICE's guidline on prevention of delirium Patients admitted for open heart surgery

Protocol summary

Summary

This research studies the influence of a multifactor-adjusted intervention based on NICE's guideline on prevention of delirium Patients admitted for open heart surgery of Imam Khomine hospital at 2014. In this semi-experimental clinical trial, 88 recruit patients are divided in two intervention and control groups. Inclusion criteria are who has no alcohol, addiction, Dementia, psychotropic drugs. Patients are removed required emergency surgery. Intervention is overcome cognitive disorders, dehydration, constipation, and infection, pain and sleep disorders. Demographic, sleep information are completed by questioners. The incidence of delirium is recorded by CAM-ICU.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403138286N5**
Registration date: **2014-05-27, 1393/03/06**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2014-05-27, 1393/03/06

Registrant information

Name

Fatemeh Bahramnezhad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

fatemeh_bahramnezhad@yahoo.com

Recruitment status

Not enough for processing

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-07-16, 1393/04/25

Expected recruitment end date

2014-07-10, 1393/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence of a multifactor-adjusted intervention based on NICE's guidline on prevention of delirium Patients admitted for open heart surgery

Public title

Multifactor-adjusted intervention based and delirium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in the study; no cognitive disorders such as dementia; no loss of hearing and vision; lack of mental disorders such as psychosis and depression; no delirium during the study; no alcoholism; open heart surgery during the study; no use drug. Exclusion criteria: unwillingness to participate in the study; require emergency open heart surgery; need for reoperation.

Age

From **65 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

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

Ethical Review Commiitee of Tehran University of Medical Sciences

Street address

Central Building, Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2014-05-20, 1393/02/30

Ethics committee reference number

93/406\130/ɔ

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.0

ICD-10 code description

Delirium, not induced by alcohol and other psychoactive substances

Primary outcomes

1

Description

Delirium

Timepoint

Every12hours

Method of measurement

CAM-ICU questioner

Secondary outcomes

1

Description

Pain

Timepoint

During painful procedure

Method of measurement

Critical care pain observation tool

2

Description

Quality of sleep

Timepoint

Daily

Method of measurement

Pittsburgh questionnaire

Intervention groups

1

Description

Intervention group: NICE guideline order (removed cognitive disorder, Dehydration, Pain, Constipation)

Category

Prevention

2

Description

Control group: Delirium of survey by CAM-ICU twice in day

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

MohammadAli cheraghi

Street address

Dr Garib St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masoud Younesian

Street address

Central Building, Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

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 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

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Hazaryan

Position

Master of nursing

Other areas of specialty/work

Street address

Nursing & Midwifery School, East Nosrat st., Tohid sq.,

City

Tehran

Postal code

Phone

+98 21 2166 9271

Fax

Email

m.hazaryan@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Bahramnezhad

Position

Ph.D

Other areas of specialty/work

Street address

Nursing & Midwifery School, East Nosrat st., Tohid sq.,

City

Tehran

Postal code

Phone

+98 21 2566 3349

Fax

Email

bahramnezhad@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Hazaryan

Position

Master of Nursing

Other areas of specialty/work

Street address

Nursing & Midwifery School, East Nosrat st., Tohid sq.,

City

Tehran

Postal code

Phone

Fax

Email

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