

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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: absence 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 participation, 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 Committee 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 hospitalization

**Method of measurement**

with CAM-ICU Scale, twice a day

**Secondary outcomes****1****Description**

length of stay

**Timepoint**

the whole of hospitalization from surgery day until discharge

**Method of measurement**

record on flowchart

**Intervention groups****1****Description**

educational delirium workshop

**Category**

Prevention

**2****Description**

installation poster on open heart surgery ward

**Category**

Prevention

**3****Description**

environmental 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 Sciences

**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 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences and Health

Services

**Full name of responsible person**

Mitra Zolfaghari

**Position**

Instructor

**Other areas of specialty/work****Street address**

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**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*