

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of use of Bispectral index monitoring on outcomes of undergoing mechanical ventilation hospitalized patients in intensive care units after open heart surgeries

Protocol summary

Summary

This study after clinical trials confirm the Shahid rajaei Heart Hospital Ethics Committee and head of the relevant sections of satisfaction. two parts simple and random ICUB and ICUA for sampling patients group and intervention(A) group are specified control(B). Using the results of a similar article (2013Maryam Mirzaie) sample size per group of 51 people. Open heart surgery is 110 people nominated to enter according to the inclusion criteria can be included and of all written consent. clinic a few days before patients by basic business information and anesthesiologist and demographic them in the form before registration. All patients in the operating room of a protocol will be entitled to the same anesthesia. For all patients to cpb connection time, duration, duration of anesthesia, aorta clamps the duration of the action in the action during the registration form. In the control group (ICUB) from the beginning of the entry of patients into the next section of the action are attached to the surface until the ventilator , according to the previous hospital routine, based on the criterion of the hemodynamic parameters and Glasgowcoma index to be measured and recorded by mental nurse. sedation level in the intervention group with the use of the CIS Any two spectral index measured for some themes and can be recorded. In both groups of medicinal drugs contain almost the same protocol to the PCA pump, persedex, Midazolam, morphine, ketrolac, apotel . For both groups in postoperative chart the amount of incoming mechanical ventilation, duration of sedating, duration of ICU stay duration of hospital admission record. then the data were analyzed by SPSS 22 case analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061428467N1**

Registration date: **2017-11-01, 1396/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Elnaz Boorghani Farahani

Name of organization / entity

Shahid Rajayi Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 23921

Email address

elnaz.farahani@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Rajayi Heart Hospital

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of use of Bispectral index monitoring on

outcomes of undergoing mechanical ventilation hospitalized patients in intensive care units after open heart surgeries

Public title
Assessment of clinical implication of bispectral index system in patient sedation

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: age range between 30 to 75 years, deduction equal 30 percent more a drain lip; the lack of a history of cerebrovascular accidents; lack of addiction to alcohol and drugs; fully under the emergency open heart surgery is not time equal less than 100 minutes aorta clamps; Cardiopulmonary bypass time less than equal to 120 minutes; during the action need to be inside the pump the aorta balloons placement; the duration of anesthesia equal less than 10 hours; total eclipses between 1-4 and without anderecthomy The exclusion criteria of the study: the patients after surgery following complications suffered are not: Myocardial infarction; cerebral and neurological complications; clotting problems; surgery; cardiac output reduction syndrome; a dangerous arrhythmias require resuscitation; pnemothorax; renal failer mechanical ventilation more than 12 hours after admission to the ICU, the trachea inside the tubing need to reset, the duration of the surgical time over 8 hours, need to re-surgery, bleeding more than 100 cc in the hours after the withdrawal of the patient from the operating room, the instability of hemodynamic status, cardiopulmonary resuscitation, the death of the patient

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

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
Shahid Rajayi Heart Center
Street address
Mellat park beside, Valiasr st, Tehran
City
Tehran
Postal code
1995614331
Approval date
2017-04-21, 1396/02/01
Ethics committee reference number
RHC.AC.TR.REC.1396.19

Health conditions studied

1

Description of health condition studied
ventilated patient in icu after open heart surgery
ICD-10 code
IX120-121-
ICD-10 code description
بیماریهای ایسکمیک قلبی

Primary outcomes

1

Description
measure of sedative drug dosage
Timepoint
while intervention
Method of measurement
bispectral index system

Secondary outcomes

1

Description
ventilation duration
Timepoint
of patient entrance to icu until extubation
Method of measurement
observation and record

Intervention groups

1

Description
" Control group: post operation icu addmition ; sedatin control according to the previous routine by nurse; Persedex PCA, midazolam, morphin, apotel, ketrolac administering according the protochol and nursing decision; consuming drug record; extubation time record; icu stay and hospital stay record."
Category
Treatment - Other

2

Description

"intervention group: post operation icu admission; connect ing bispectral index system to pateint from arrival time to extubation time and sedation score record per 2 hours; drug administering according bis score and the protochol; consuming drug record; extubation time record; icu stay and hospital stay record. "

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajayi Hospital

Full name of responsible person

Elnaz Boorghni Farahani

Street address

Mellat Park beside, Valiasr st, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Shahid Rajayi Heart Center

Full name of responsible person

Mr Dr Mostafa Alavi

Street address

Mellat Park beside, Valiasr st, Tehran.

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 Shahid Rajayi Heart Center

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

Shahid Rajayi Heart Center

Full name of responsible person

Elnaz Boorghni Farahani

Position

Critical Care Master student of Shahid Rajayi Center

Other areas of specialty/work

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Position

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Person responsible for updating data

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