Clinical Trial Protocol
Iranian Registry of Clinical Trials
15 Feb 2020

The effect of Riker Sedation-Agitation scale on clinical outcomes in patients undergoing coronary artery bypass graft surgery in Imam Ali Hospital

Protocol summary

Summary
Objective: to determine the effect of Riker Sedation-Agitation scale on clinical outcomes in patients undergoing coronary artery bypass graft surgery in Imam Ali hospital, Kermanshah, Iran.
Study design: Randomized. Study population: Patients undergoing open heart surgery and admitted to the intensive care unit at Imam Ali hospital. Major inclusion criteria: having an endotracheal tube, being under mechanical ventilation, having acceptable clinical and para clinical criteria such as left ventricular ejection fraction greater than 30% and lack history of cerebrovascular accident. Major exclusion criteria: mechanical ventilation for more than 24 hours, need to reintubation, length of operation time more than 4 hours, requiring reoperation. Sample Size: 116 patients.
Intervention: each hour in the intervention group, the patients were evaluated using Riker scale and based on patients receiving sedative medication and in the control group, based on the physiological criteria, medicine was given. Intervention time: The patient's arrival to the intensive care unit until extubation. Primary outcomes: sedative usage, length of mechanical ventilation and length of stay in intensive care unit and hospital, delirium incidence.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT201209244736N4
Registration date: 2012-11-28, 1391/09/08
Registration timing: registered_while_recruiting

Country
Iran (Islamic Republic of)
Phone
+98 83 3827 9394
Email address
akhatony@kums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research & technology, Kermanshah university of medical sciences

Expected recruitment start date
2012-11-21, 1391/09/01
Expected recruitment end date
2013-02-18, 1391/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Riker Sedation-Agitation scale on clinical outcomes in patients undergoing coronary artery bypass graft surgery in Imam Ali Hospital

Public title
The effect of Riker sedation-agitation scale on clinical outcomes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: 1. Having coronary artery bypass graft surgery. 2. Having acceptable clinical and paraclinical criteria such as adequate tissue perfusion. 3. Age between 40-70 years old. 4. Lack of visual and listening problems. 5. Left ventricular ejection fraction more than 30%. 6. Lack of cerebrovascular accidents. 6. Number of grafts between 1-4 without endarterectomy. Exclusion criteria: 1. If the patient suffering from one of these disease after surgery: MI, CVA, coagulopathy, reoperation, dangerous arrhythmia, renal failure, wound...
infection, mechanical ventilation more than 24 hour, need to reintubation, operation time more than 4 hour.

**Age**
From 40 years old to 70 years old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
No information

**Sample size**
Target sample size: 116

**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
Kermanshah university of medical sciences

Street address
Sepah Pasdaran sq. shahid beheshty bld.

City
Kermanshah

Postal code

Approval date
2012-10-23, 1391/08/02

Ethics committee reference number
33970

**Health conditions studied**

1

**Description of health condition studied**
clinical outcomes

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**
ventilation duration

**Timepoint**

**Method of measurement**
measurement of ventilation time

2

**Description**
opium consumption dose

**Timepoint**
after extubation

**Method of measurement**
Recorded data of checklist during the intervention

**Secondary outcomes**

1

**Description**
delirium incidence

**Timepoint**
during stay in ICU

**Method of measurement**
delirium screening checklist in intensive care units

2

**Description**
length of stay in hospital

**Timepoint**
after discharge from hospital

**Method of measurement**
time of entry and exit from hospital

3

**Description**
length of stay in ICU

**Timepoint**
after discharge from ICU

**Method of measurement**
Based on the time of entry and exit

**Intervention groups**

1

**Description**
In this study in intervention group, the researcher assesses the sedation and agitation level of patients with Riker scale. The optimal level of Riker scale is 3,4 score

**Category**
Prevention

2

**Description**
In control group is used from routine method. This method is based on the physiologic and behavioral criteria such as vital signs and first awakening.

**Category**
Prevention
Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali hospital
Full name of responsible person
Dr Gholamreza Morady
Street address
Sepah pasdaran sq. shahid beheshty bld.
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah university of medical sciences
Full name of responsible person
Dr Farid Najafy
Street address
Kermanshah university of medical sciences, sepah pasdaran sq. shahid beheshty bld.
City
Kermanshah
Grant name
Title of funding source
Kermanshah 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
school of paramedical science
Full name of responsible person
Reza Pourmirza Kalhori
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Person responsible for updating data

Contact
Name of organization / entity
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http://nursing-school.kums.ac.ir/
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