

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

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**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

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Name of organization / entity

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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%, 5. 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 24hour, 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
after extubation
Method of measurement
measurment 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 intansive care units

2

Description
lenght of stay in hospital
Timepoint
after discharge from hospital
Method of measurement
time of entry and exit from hospital

3

Description
lenght 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 assess the sedation and agitation level of patients with Riker scale. 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

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

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

Position

MSc, faculty member

Other areas of specialty/work

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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