

# 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

##### Name

Alireza Khatony

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### 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%, 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

#### Street address

Doolat abbad, ashayer bld.

#### City

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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MSc of nursing/ faculty member

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Kermanshah school of nursing and midwifery

#### Full name of responsible person

Alireza khatony

#### Position

PhD-faculty member

#### Other areas of specialty/work

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**Web page address**

<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*