

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of controlled sedation based Richmond tool on clinical outcomes in mechanically ventilated patients admitted to intensive care units

Protocol summary

Summary

This study aimed to determine the effect of controlled sedation based Richmond- tool on clinical outcomes in mechanically ventilated patients admitted to intensive care in the hospital in Rasht in 2017. This study is a randomized and single center. Inclusion criteria include patients undergoing coronary artery bypass graft that receiving mechanical ventilation in ICU; patients are receiving the sedation drugs. Patients ages 30 to 70 years old, after the operation requires mechanical ventilation for less than 24 hours and the number one to four arterial grafts without the need Endarterectomy; lack of hearing and vision problems or difficulty in understanding the language of Persian, exclusion criteria included Patients with postoperative cardiac and respiratory arrest and need to re-operation due to abnormal bleeding. The number of samples in each group computed 40 patients in that randomized block design are divided the blocks A and B. the Richmond tool used for evaluation the sedation level of patients in the intervention group. but the control group received routine. COPT tool measuring pain in both groups. Two groups are compared duration of mechanical ventilation and the hemodynamic parameters

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050517693N2**

Registration date: **2017-05-24, 1396/03/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-24, 1396/03/03

Registrant information

Name

Mohammad Reza Yeganeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of controlled sedation based Richmond tool on clinical outcomes in mechanically ventilated patients admitted to intensive care units

Public title

The effect sedation level on weaning of mechanical ventilation

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing coronary artery

bypass graft (CABG); From ages 30 to 70 years old; Need for mechanical ventilation for less than 24 hours after the operation; The number of one to four arterial grafts without the need to Endarectomy; Lack of hearing and vision problems or difficulty in understanding the language of Persian Exclusion criteria: Cardiac and respiratory arrest after surgery; The need for re-operation due to abnormal bleeding

Age

From **17 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Ethic Committee of Guilan University of Medical Sciences, Vice chancellor for research

Street address

Opposite bank sepah, Boulevard Martyr Beheshti western, Rasht

City

Rasht

Postal code

41938-93345

Approval date

2017-04-29, 1396/02/09

Ethics committee reference number

IR.GUMS.REC.1396.37

Health conditions studied

1

Description of health condition studied

mechanical ventilation duration

ICD-10 code

T81.8, Z51

ICD-10 code description

Other complications of procedures, not elsewhere classified , Other specified medical care

Primary outcomes

1

Description

sedation level

Timepoint

intervention time

Method of measurement

richmond scale

2

Description

pain

Timepoint

intervention time

Method of measurement

COPT scale

3

Description

mechanical ventilation duration

Timepoint

intervention time

Method of measurement

hour

4

Description

the amount of using of sedative

Timepoint

intervention time

Method of measurement

mg,mcigram/h , based on a sedation

Secondary outcomes

1

Description

Length of stay in Hospital

Timepoint

discharge or dead

Method of measurement

day

2

Description

Length of stay in ICU

Timepoint

discharge of ICU

Method of measurement

hour

3

Description

median arterial pressure

Timepoint

intervention time

Method of measurement

mmHG with manitor

4

Description

body mass index

Timepoint

before intervention

Method of measurement

weight by meters squared

5

Description

pulse pressure

Timepoint

intervention time

Method of measurement

mmHG with manitor, difference between SBPand DBP

6

Description

pulse rate

Timepoint

intervention time

Method of measurement

bpm with monitor

7

Description

o2 saturation

Timepoint

intervention time

Method of measurement

percentage

Intervention groups

1

Description

Intervention group: Mechanically ventilated patients receive the amount of sedative based on Richmond scale measured every hour the sedation level

Category

Other

2

Description

Control group: Mechanically ventilated patients receive routinely the amount of sedative without used agitation sedation scales

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Heart Dr Heshmat

Full name of responsible person

Mohammad Reza Yeganeh

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15 Azar St, next to Management and PlaningOrganization

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Sponsors / Funding sources

1

Sponsor

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Guilan University of medical Sciences, Vice chancellor for research

Full name of responsible person

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Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan University of medical Sciences, Vice chancellor for research

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

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Full name of responsible person

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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