

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of protocol-directed versus conventional-directed weaning for reducing the duration of mechanical ventilation in cardiac surgery patients who developed AKI.

Protocol summary

Study aim

comparison the effect of weaning protocol vs conventional method on the duration of mechanical ventilation in cardiac surgery patients who developed AKI

Design

Clinical trials with intervention and control group, randomized

Settings and conduct

In November 2013, Rajaie cardiovascular medical and research center adopted a mechanical ventilation weaning protocol (WM 42-05) . The study is a randomized controlled trial in which 100 patients with acute kidney injury after open heart surgery will allocate to either the protocol-directed (intervention=50) or the conventional-directed (control=50) group.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1- age 18–75 years 2- Increase in serum creatinine ≥ 0.3 mg/dL or urine output < 0.5 ml/kg/hour for ≥ 4 hours 3- no previous open-heart surgery. Exclusion criteria: Patients who return to the operating room

Intervention groups

patient weaning from ventilator based on protocol

Main outcome variables

The duration of mechanical ventilation, creatinine and urea levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190221042783N1**

Registration date: **2019-06-12, 1398/03/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-12, 1398/03/22**

Update count: **0**

Registration date

2019-06-12, 1398/03/22

Registrant information

Name

hojjat asadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8849 8210

Email address

asadzadeh@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of protocol-directed versus conventional-directed weaning for reducing the duration of mechanical ventilation in cardiac surgery patients who developed AKI.

Public title

The effect of ventilator weaning protocol on duration of mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with open heart surgery Post-operative open heart surgery patients aged between 18 and 75 Patients who have a ceratinin level of 1/5 after heart surgery

Exclusion criteria:
Cardio-pulmonary resuscitation of the patient History of hemodialysis patient

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

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

Ethics Committee of Shahid Rajaee Cardiovascular Research Center

Street address

no 1, West 6, Janbazan Ave, Golbarg Blvd, Majedeyeh

City

tehran

Province

Tehran

Postal code

1333715914

Approval date

2018-06-11, 1397/03/21

Ethics committee reference number

93072

Health conditions studied

1

Description of health condition studied

Acute renal failure

ICD-10 code

N17.8

ICD-10 code description

Other acute renal failure

Primary outcomes

1

Description

Effect of weaning protocol from ventilator on mechanical ventilation time

Timepoint

Every two hours after surgery

Method of measurement

Measurement based on hours after surgery

Secondary outcomes

1

Description

The effect of protocol on the level of creatinine and blood urea

Timepoint

Every two hours after the surgery

Method of measurement

Based on hours

Intervention groups

1

Description

Intervention group: After the open heart surgery, the patients will transfer to CCU . In the Intervention group patients will separate from ventilator based on adopted mechanical ventilation weaning protocol (WM 42-05) and ventilation time will recorded. In this protocol, based on patient's readiness and considering the criteria and patient's status based on the protocol, some parameters (respiratory rate, arterial oxygen saturation, consciousness, minute volume and effective cough) will be evaluated.

Category

Treatment - Devices

2

Description

Control group: After the open heart surgery, the patients will transfer to CCU . In the control group patients will separate from ventilator based on conventional method and ventilation time will recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Cardiovascular Research Center

Full name of responsible person

Hojjat Allah Asadzadeh

Street address

No.1, West6, Janbazan Ave, Golbarg Blv, Majedeyeh

City

Tehran

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Postal code

1333715914

Phone

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Email

asadzadeh@rhc.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hojjat Allah Asadzadeh

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asadzadeh59hojjat@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Research Center for Shahid Rajaee Heart and Ascension

Full name of responsible person

Hojjat Allah Asadzadeh

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available