

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the Trachea extubation in the operation room in open heart surgery with cardiopulmonary bypass using various anesthesia monitoring

Protocol summary

Study aim

Assessment of the trachea extubation in the operation room after open heart surgery with cardiopulmonary bypass using various anesthesia screening compared with conventional extubation in intensive care unit

Design

This is a single-blinded clinical trial. 100 eligible patients were allocated in two groups by simple randomization: one group received conventional extubation in the intensive care unit and the other underwent extubation in the operation room. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

This single-blinded randomized clinical trial was conducted in Rajaie Cardiovascular Medical and Research Center. For blinding, patients were unaware of the group they were allocated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-65 years of age BMI $\geq$ 18-25 kg/m² LVEF>35% Without history of myocardial infarction during the last seven days Not having COPD Emphysema Not receiving potent inhalation drugs Exclusion criteria: Receiving inotropes for hemodynamic support before operation Needing reoperation due to surgical adverse outcomes like bleeding Not cooperating during the first days after operation

Intervention groups

Group one: trachea extubation in the intensive care unit
Group two: trachea extubation in the operation room

Main outcome variables

Arterial blood gas analysis; systolic and diastolic blood pressure; heart rate; inotrope need; amount of anesthetics use; blood and transfusion products

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161220031487N7**

Registration date: **2018-03-14, 1396/12/23**

Registration timing: **retrospective**

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

Registration date

2018-03-14, 1396/12/23

Registrant information

Name

مهرداد Mesbah kiaei

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 346 5866

Email address

dr.mmesbah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date

2018-01-21, 1396/11/01

Trial completion date

empty

Scientific title

Assessment of the Trachea extubation in the operation room in open heart surgery with cardiopulmonary bypass using various anesthesia monitoring

Public title

Effects of anesthesia monitoring on trachea extubation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate for elective coronary artery bypass grafting operation Body mass index of 18-25 kg/m² LVEF>35%

Exclusion criteria:

Receiving inotropes for hemodynamics support before operation Needing reoperation due to surgery-related complications such as bleeding Not cooperating in the early post-operative days Myocardial Infarction in the 7 recent days Emphysema Needing reoperation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using excel software and random number assignment with concealment of allocation

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are unaware of the group they are allocated.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of the Iran University of Medical Sciences

Street address

Hemmat highway, next to Milad Tower

City

Tehran

Province

Tehran

Postal code

1416771818

Approval date

2017-11-05, 1396/08/14

Ethics committee reference number

IR.IUMS.FMD.REC 1396.06818767611

Health conditions studied**1****Description of health condition studied**

Ischaemic heart diseases

ICD-10 code

I20-I25

ICD-10 code description

Ischaemic heart diseases

Primary outcomes**1****Description**

Systolic blood pressure

Timepoint

Intensive care unit entrance

Method of measurement

Barometer and vital sign monitoring device

2**Description**

Use of anesthetics

Timepoint

During operation

Method of measurement

Calculating and registering the amount of the medication used

3**Description**

Using inotropes

Timepoint

In operation room and in ICU

Method of measurement

Calculating and registering the amount of medication used.

4**Description**

Diastolic blood pressure

Timepoint

Intensive care unit entrance

Method of measurement

Barometer and vital sign monitoring device

5**Description**

Heart rate
Timepoint
Intensive care unit entrance
Method of measurement
Vital sign monitoring device

Secondary outcomes

1

Description

Arterial blood gas analysis

Timepoint

Before anesthesia induction and on intensive care unit entrance

Method of measurement

Blood gas analysis device

Intervention groups

1

Description

Intervention group: trachea extubation in the operation room- The nature of this intervention is the use of short-acting drugs and multiple anesthetic monitoring, and muscle and cardiovascular relaxation in patients with open heart surgery with cardiopulmonary bypass, in order to maintain adequate depth of anesthesia and maintain stable hemodynamics. At the end of the anesthesia, with neutralizing the effect of medications and maintaining the adequate analgesia and hemodynamic stability, and to ensure adequate surgical homeostasis, the patient is extubated in the operation room and transferred to the ICU.

Category

Treatment - Other

2

Description

Control group: extubation in the intensive care unit- The patient receives the usual anesthetic, and after transfer to the intensive care unit, the condition of the tracheal tube is sustained until the hemodynamic stability, and mechanical ventilation is performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Ziae Totonchi

Street address

Niyayesh Exp., Valiasr cross.

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ziya189@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Kazem Malekouti

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Next to Milad Tower, Hemmat Exp.,

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research@iums.ac.ir

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

Iran University of Medical Sciences

Full name of responsible person

Ziya Totonchi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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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

There is no further 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available