

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of mechanical ventilation during cardiopulmonary bypass surgery in adult cardiac valve surgery on inflammatory responses and pulmonary function

Protocol summary

Study aim

Evaluation of the effect of mechanical ventilation during cardiopulmonary bypass surgery in adult cardiac valve surgery on inflammatory responses and pulmonary function

Design

This study is a clinical trial study that is performed after the approval of the ethics committee and after obtaining informed written consent from all patients in Shahid Rajaei Heart Center. This study is performed over a period of 18 months and according to the statistical calculation, 30 patients are examined in each group.

Settings and conduct

This study will be performed in the operating room of Shahid Rajaei Cardiovascular Research Center. All patients underwent PFT and 6 minute walking test before surgery. In all patients in both groups, inflammatory cytokines before and after CPB will be measured also after extubation in ICU. And are compared in both groups, also PFT and 6min test are performed on the seventh day after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: □ All adult patients undergoing elective cardiac valve surgery
Exclusion criteria: o Emergency surgery
o Congenital heart surgery
o Patients undergoing third and more valve resections
o Patients with coagulation disease
o Patients undergoing dialysis
o Patients with pulmonary problems
o fractional ejection less than 35%,
o Patients with open sternum
o if the surgeon's vision decreases during cardiac surgery due to continued mechanical ventilation, the ventilation will stop
o patients who remain intubated for more than 12 hours
o patients who are transferred to the operating room for any reason

Intervention groups

In this study, mechanical ventilation with TV = 3cc / Kg, RR = 6, PEEP = 5 and FI02 = 1 continues in the

intervention group during cardiopulmonary bypass.

Main outcome variables

IL-6, IL-8, IL-10,INT gamma, TNF alph; respiratory test; duration of stay in the intensive care unit and hospital
(ویرایش شد)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211026052875N1**
Registration date: **2021-11-21, 1400/08/30**
Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**

Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

Shima Hadipourzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 3740

Email address

shimahadipourzadeh@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mechanical ventilation during cardiopulmonary bypass surgery in adult cardiac valve surgery on inflammatory responses and pulmonary function

Public title

The effect of mechanical ventilation during cardiopulmonary bypass surgery in adult cardiac valve surgery on inflammatory responses and pulmonary function

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

□ All adult patients with age >35y undergoing elective cardiac valve surgery

Exclusion criteria:

patients undergoing emergency surgery Patients undergoing congenital heart surgery Patients undergoing third and more valve resections Patients with coagulation disease Patients undergoing dialysis Patients with pulmonary problems such as COPD who are in stage one and four due to FEV1 (stage1:mild FEV1 \geq 80%, stage2:moderate FEV1 50-79%, stage3:severe FEV130-49% , stage 4: very severe FEV1 \leq 30%) Patients with fractional ejection less than 35%, Patients who transfer to the ICU with open sternum In this study, if the surgeon's vision decreases during cardiac surgery due to continued mechanical ventilation, the ventilation will stop and the patient will be excluded from the study Patients who remain intubated for more than 12 hours after transfer to the ICU due to hemodynamic instability patients who are transferred to the operating room for any reason

Age

From **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of block randomization. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are

required during the sampling process. The size of all blocks is the same and we will have 2 groups of 6 blocks in this two-group experiment, including 3 participants in the intervention group and 3 participants in the control group. Random allocation software is also used for randomization tools. In addition to simple randomization, these random sequence generation software is able to generate random sequences by blocking method. For concealment, we use allocation concealment, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with a random sequence in (Sequentially numbered, sealed, opaque envelopes) this method, each of the random sequences created is recorded on a card and the cards in the envelopes to They are placed in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The anesthesiologist and the laboratory are aware of blindness in the study group, but, patient is unaware of the study group, and the study is one-sidedly blind. The patients are explained that they are in one of the two study groups and the patients are anesthetized during the operation and remains unaware of which group they are in.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Rajaei Cardiovascular Research Center.

Street address

Ayatollah Hashemi Highway, cross valiasr Ave. Shahid Rajai Hospital

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2021-03-06, 1399/12/16

Ethics committee reference number

IR.RHC.REC.1399.130

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

Diseases of the respiratory system

ICD-10 code

J96.0

ICD-10 code description

Acute respiratory failure

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

Inflammatory cytokines (IL-6, IL-8, IL-10, INT gamma, TNF alph)

Timepoint

After induction of anesthesia and placement of the central vein; after separation from cardiopulmonary bypass; after extubation

Method of measurement

Inflammatory cytokines using venous blood samples in operation room and ICU

2**Description**

Respiratory test

Timepoint

The day before surgery, the seventh day after surgery

Method of measurement

PFT and 6min Walking test before and after surgery

Secondary outcomes**1****Description**

length of stay in hospital and intensive care unit

Timepoint

After discharge from hospital

Method of measurement

length of stay in hospital and intensive care unit according to patient records

Intervention groups**1****Description**

Intervention group: In this study, mechanical ventilation with TV = 3cc / Kg, RR = 6, PEEP = 5 and FIO2 = 1 continues in the intervention group during cardiopulmonary bypass and blood samples are sent for

inflammatory cytokines before and after cardiopulmonary bypass.

Category

Prevention

2**Description**

Control group: Control group: In this group, mechanical ventilation is stopped during cardiopulmonary bypass and blood samples are sent for inflammatory cytokines before and after cardiopulmonary bypass.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rajaie Cardiovascular, Medical and Research Center

Full name of responsible person

Saeid Hosseini

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Ayattollah Hashemi Highway, cross valiasr Ave.
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number**

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

Title of funding source
Rajaie Cardiovascular, Medical and Research Center

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
Fatemeh shima Hadipourzadeh

Position
assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Full name of responsible person
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Position
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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period 6 months after printing the results

To whom data/document is available

It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

To be aware of the study results and, if desired, use the results in other centers

From where data/document is obtainable

They can refer to the person in charge of scientific responsibility

What processes are involved for a request to access data/document

The application will be emailed to the applicant within two weeks

Comments