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 (ویرایش‌شد)

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≥80%، stage2:moderate FEV1 50-79%، stage3:severe FEV130-49% ، stage 4: very severe FEV1 ≤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
Ayattollah 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 FI02 = 1 continues in the intervention group during cardiopulmonary bypass and blood samples are sent for inflammatory cytokines beforeand 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 beforeand 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
Street address
Ayattollah Hashemi Highway, cross valiasr Ave. Shahid Rajai Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rajaie Cardiovascular, Medical and Research Center
Full name of responsible person
Saeideh Mazloomzadeh
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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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Person responsible for updating data

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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