

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

comparison of the effect of retrograde autologous(rap) priming technique during extracorporeal circulation on blood transfusion rate in adult patients undergoing heart valve surgery

Protocol summary

Study aim

Evaluation of the effect of rap technique during extracorporeal circulation on blood transfusion rate in adult patients undergoing heart valve surgery

Design

This study was a randomized controlled clinical trial in the control and intervention groups is done.25 patients in each group(50 patients generally)in parallel

Settings and conduct

the study was performed on patients undergoing cardiac valve surgery.inclusion criteria include these items: cardiac valve replacement surgery;cardiac surgery with cardiopulmonary bypass;patienes with age over 18years.the patient enters the study randomly by choosing a blue or red card and in the control or intervention group.The study site is the operating and intensive care unit of afshar hospital in yazd province. blinding is not done in the study.with the knowledge of surgeon and anesthesiologist in the intervention group after priming the tubes with crystalloid fluid and before the start of extracorporeal circulation the clamp is removed from the arterial tube and then intravenously until the tubes are filled with the patients own blood and excess crystalloid fluid is removed from the circuit.in the control group the circuit is usually prime with crystalloid fluid and extracorporeal circulation begins.

Participants/Inclusion and exclusion criteria

Inclusion criteria:cardiac valve replacement surgery.age over 18 years.cardiopulmonary bypass . weight over 30kg.EF OVER 20%. Exclusion criteria:emergency surgery. thrombocytopenia. cardiac surgery that requires deep hypothermia. chronic kidney diseases

Intervention groups

group of patients performing the technique retrograd autologous priming and group of patients without technique retrograd autologous priming

Main outcome variables

blood transfusion rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200824048506N1**

Registration date: **2020-09-22, 1399/07/01**

Registration timing: **retrospective**

Last update: **2020-09-22, 1399/07/01**

Update count: **0**

Registration date

2020-09-22, 1399/07/01

Registrant information

Name

Raziyeh Khodsiyani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3862

Email address

raz201364@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-10-21, 1398/07/29

Actual recruitment start date

2019-01-29, 1397/11/09

Actual recruitment end date

2019-10-21, 1398/07/29

Trial completion date

2019-10-24, 1398/08/02

Scientific title

comparison of the effect of retrograde autologous(rap) priming technique during extracorporeal circulation on blood transfusion rate in adult patients undergoing heart valve surgery

Public title

"assessing the effectiveness of retrograde autologous priming on blood transfusion"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

cardiac valve replacement surgery cardiac surgery whit cardiopulmonary bypass patienes whit age over 18 years

Exclusion criteria:

ejection fraction less than 20% weight less than 30 kg emergency surgery thrombocytopenia surgery requires deep hypothermia chronic kidney disease

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

According to red and blue cards that choice by the patient herself

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 yazd shahid sadoughi university of medical sciences

Street address

boolvar shohadaie ghomnam

City

yazd

Province

Yazd

Postal code

8199966897

Approval date

2019-07-02, 1398/04/11

Ethics committee reference number

ir.ssu.medicine.rec.1398.098

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

Cardiac surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

evaluation of RAP technique in blood intake

Timepoint

befor surgery.during surgery.time of hospitalization in ICU. discharge time

Method of measurement

getting blood sample and record the values in the questionnaire form

Secondary outcomes

empty

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

Intervention group: patients with heart valve problems who undergo RAP technique and surgery during cardiopulmonary bypass

Category

Treatment - Devices

2**Description**

Control group: patients with heart valve problem who do not receive retrograde autologous priming undergo surgery and cardiopulmonary bypass

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center**

Name of recruitment center

afshar general hospital
Full name of responsible person
Dr.Abdollahi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr hadadzadeh
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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

Yazd University of Medical Sciences

Proportion provided by this source

10

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
Yazd University of Medical Sciences
Full name of responsible person

raziyeh khodsiani
Position
perfusionist
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to

make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to
make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to
make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable