

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of ringer with ringer lactate as a prime solution in coronary artery bypass graft

Protocol summary

Study aim

Comparison of ringer with ringer lactate as a prime solution in coronary artery bypass graft

Design

Double Blinded Randomized Clinical Trial

Settings and conduct

Intervention group1: Oxygenator content contains 1600 cc of prime solution including heparin, hydroxyethyl starch and ringer. Intervention group2: Oxygenator content contains 1600 cc of prime solution including heparin, hydroxyethyl starch and Ringer's lactate.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:Patients Candidate for Coronary Artery Bypass Graft Surgery, Age 20 to 75 years ,Weight less than 50 kg and over 100 kg, Acid-disorder disturbance
Exclusion Criteria:Cardiopulmonary pump duration over 6 hours, Emergency surgery, Chronic renal failure, Anemia (Hb <10 g / dl), Coagulopathy ,Pulmonary Failure ,Diabetes mellitus, Liver problem, Acid-disorder disturbance.

Intervention groups

Intervention group1: Oxygenator content contains 1600 cc of prime solution including heparin, hydroxyethyl starch and ringer. Intervention group2: Oxygenator content contains 1600 cc of prime solution including heparin, hydroxyethyl starch and Ringer's lactate.

Main outcome variables

Blood PH ,Serum bicarbonate level ,Base excess ,PaCO2 .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N94**

Registration date: **2020-01-10, 1398/10/20**

Registration timing: **prospective**

Last update: **2020-01-10, 1398/10/20**

Update count: **0**

Registration date

2020-01-10, 1398/10/20

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ringer with ringer lactate as a prime solution in coronary artery bypass graft

Public title

Comparison of ringer with ringer lactate as a prime solution in coronary artery bypass graft

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients Candidate for Coronary Artery Bypass Graft Surgery Age 20 to 75 years Weight less than 50 kg and over 100 kg

Exclusion criteria:

Cardiopulmonary pump duration over 3 hours Emergency surgery Chronic renal failure Anemia (Hb <10 g / dl) Coagulopathy Pulmonary Failure Diabetes mellitus Liver problem Acid-disorder disturbance

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups of 27 using the table from [www.randomization .org](http://www.randomization.org).

Blinding (investigator's opinion)

Double blinded

Blinding description

Primer solution is provided by a person who does not know the study groups and it is provided by a perfusionist. The patient, clinical caregiver, and outcome assessor will not be aware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2019-07-24, 1398/05/02

Ethics committee reference number

IR.SUMS.MED.REC.1398.298

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Graft Surgery

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Blood PH

Timepoint

15 minutes after the start of cardiopulmonary bypass, in the warm-up phase at 34 ° C.

Method of measurement

Arterial blood sample

2

Description

Serum bicarbonate level

Timepoint

15 minutes after the start of cardiopulmonary bypass, in the warm-up phase at 34 ° C.

Method of measurement

Arterial blood sample

Secondary outcomes

1

Description

Base excess

Timepoint

15 minutes after the start of cardiopulmonary bypass, in the warm-up phase at 34 ° C.

Method of measurement

Arterial blood sample

2

Description

PaCO2

Timepoint

15 minutes after the start of cardiopulmonary bypass, in the warm-up phase at 34 ° C.

Method of measurement

Arterial blood sample

Intervention groups

1

Description

Intervention group1: Oxygenator content contains 1600 cc of prime solution including heparin, hydroxyethyl starch and ringer.

Category

Prevention

2

Description

Intervention group2: Oxygenator content contains 1600 cc of prime solution including heparin, hydroxyethyl starch and Ringer's lactate.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Ghasem Ghasempour

Street address

Faghihi Hospital, Zand Street

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7134814336

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2

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Ghasem Ghasempour

Street address

Namazi Hospital, Namazi Square

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1331171936

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nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

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Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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sacrc@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Ghasem Ghasempour

Position

perfusionist

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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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

Its against our policies.

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