

# 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**

Etichs Committee of Shiraz Univesrity 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

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

##### Phone

+98 71 3227 9701

##### Email

faghihihsp@sums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Namazi Hospital

##### Full name of responsible person

Ghasem Ghasempour

##### Street address

Namazi Hospital, Namazi Square

##### City

Shiraz

##### Province

Fars

##### Postal code

1331171936

##### Phone

+98 71 3647 4332

##### Email

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

##### Street address

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

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

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

##### Street address

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

##### City

Shiraz

##### Province

Fars  
**Postal code**  
7134844119  
**Phone**  
+98 71 3647 4270  
**Email**  
ghasemghasempoor@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Bahram Ghasemzadeh  
**Position**  
Cardiac surgeon  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Cardiology  
**Street address**  
Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street  
**City**  
Shiraz شیراز  
**Province**  
Fars  
**Postal code**  
7134844119  
**Phone**  
+98 71 3647 4270  
**Email**  
ghasemzadeh@sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences  
**Full name of responsible person**  
Farzaneh Masihi  
**Position**  
BS in anesthesia/English Consultant  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
5th floor, Mohammad Rasoul Allah Research Tower, Khalili Street  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134844119  
**Phone**  
+98 71 3647 4270  
**Email**  
masihifarzaneh@yahoo.com

## 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