

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of effect of ringer's solution and lactated ringer as prime solution on acidosis and lactate level in noncyanotic pediatric cardiac surgery

Protocol summary

Study aim

effect of ringer and lactated ringer as prime solution on acidosis and lactate level in noncyanotic pediatric cardiac surgeries

Design

50 children undergoing open heart surgery are randomly divided into two groups. This clinical trial with two parallel groups will be double blinded.

Settings and conduct

This study will be conducted in the operating room of Shahid Rajaei Heart Center and patients and the surgical team will be unaware of the type of solution used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with non-cyanotropic heart disease, Having consent from the parents of the patient, Non-emergency surgery, Absence of coagulation disorders. Absence of anemia (hemoglobin less than 10 g / dl), Absence of hepatic impairment, Absence of kidney failure, Absence of lung failure, Absence of diabetes, Absence of acid disorder and severe preoperative hypertension, Lactate levels greater than 2 mM per liter before surgery, Not having a history of heart surgery (redo) Exclusion criteria: Periods of arterial blood pressure reduction before surgery, Ultrafiltration during bypass

Intervention groups

Intervention group, lactated ringer 350 to 400 cc, once at onset bypass. Control group, Ringer's solution 350 to 400 cc, once at onset bypass.

Main outcome variables

The variables of pH, Bicarbonate, Base Excess, Chloride, Lactate and the amount of sodium bicarbonate injected will be recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180407039222N1**

Registration date: **2018-07-08, 1397/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-08, 1397/04/17**

Update count: **0**

Registration date

2018-07-08, 1397/04/17

Registrant information

Name

Davood Samiei

Name of organization / entity

Shaheed Rajaei Cardiovascular Medical and Research Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2454

Email address

samieidavood@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-06, 1397/04/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of ringer's solution and lactated ringer as prime solution on acidosis and lactate level in noncyanotic pediatric cardiac surgery		Ethic comittee of Shahid Rajai Cardiovascular Medical and Research Center	
Public title	Comparison of Ringer and Ringer Lactate Solution on Acidose and Lactate Status in Pediatric Heart Surgery	Street address	Ayattollah Hashemi Highway, cross Vali-asr Ave.Shahid Rajai Cardiovascular, Medical and Research Heart Center
Purpose	Prevention	City	Tehran
Inclusion/Exclusion criteria		Province	Tehran
Inclusion criteria:	Children with non-cyanotropic heart disease Having consent from the parents of the patient Non-emergency surgery Absence of coagulation disorders Absence of anemia (hemoglobin less than 10 g / dl) Absence of hepatic impairment Absence of kidney failure Absence of lung failure Absence of diabetes Absence of acid disorder and severe preoperative hypertension Lactate levels greater than 2 mM per liter before surgery Not having a history of heart surgery (redo) Age 12 to 48 months	Postal code	19956114331
Exclusion criteria:	Periods of arterial blood pressure reduction before surgery Ultrafiltration during bypass	Approval date	2017-03-04, 1395/12/14
Age	From 12 months old to 48 months old	Ethics committee reference number	RHC.AC.IR.REC.1395.42
Gender	Both	Health conditions studied	
Phase	1-2	1	
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor	Description of health condition studied	
Sample size	Target sample size: 50	Metabolic Acidosis	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
Randomization description	Simple randomization, lottery through sealed envelopes	E87.2	
Blinding (investigator's opinion)	Double blinded	ICD-10 code description	
Blinding description	Participating patients,Responsible perfusionist and Responsible for data collection were kept blind.	Acidosis	
Placebo	Not used	Primary outcomes	
Assignment	Parallel	1	
Other design features		Description	
Secondary Ids	empty	pH level	
Ethics committees		Timepoint	
1		Before the onset of cardiopulmonary bypass and during anesthesia, 5 minutes, 30 minutes and one hour after the onset of cardiopulmonary bypass.	
Ethics committee		Method of measurement	
Name of ethics committee		Arterial blood sample and arterial gas analyzer	
		2	
		Description	
		Blood lactate level	
		Timepoint	
		Before the onset of cardiopulmonary bypass and during anesthesia, 5 minutes, 30 minutes and one hour after the onset of cardiopulmonary bypass.	
		Method of measurement	
		Arterial blood samples and Care diagnostica machine	
		3	
		Description	
		Arterial blood bicarbonate level	
		Timepoint	
		Before the onset of cardiopulmonary bypass and during anesthesia, 5 minutes, 30 minutes and one hour after the onset of cardiopulmonary bypass.	
		Method of measurement	
		Arterial blood sample and arterial gas analyzer	

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Description

Arterial base excess level

Timepoint

Before the onset of cardiopulmonary bypass and during anesthesia, 5 minutes, 30 minutes and one hour after the onset of cardiopulmonary bypass.

Method of measurement

Arterial blood sample and arterial gas analyzer

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Description

Arterial blood chloride level

Timepoint

Before the onset of cardiopulmonary bypass and during anesthesia, 5 minutes, 30 minutes and one hour after the onset of cardiopulmonary bypass.

Method of measurement

Arterial blood sample and arterial gas analyzer

Secondary outcomes

1

Description

The amount of sodium bicarbonate injected to correct acidosis

Timepoint

5 minutes, 30 minutes and one hour after the start of the bypass

Method of measurement

observation

Intervention groups

1

Description

Intervention group: In the first group, a lactate ringer solution will be used to prepare the cardiopulmonary bypass system. Also, the venofundin 6% etherified starch solution at 15 cc / kg body weight, heparin 3 units per ml of prime solution, sodium bicarbonate at 24 mEq / l of prime solution and Mannitol 0.5 grams per kilogram of body weight will be added. In the case of low hematocrit, packed cell will also be used. The amount of lactated ringer solution will be about 350-400 cc and once at the start of the bypass. The Ringer Lactate solution is the product of Shahid Ghazi Tabriz factory and made in Iran.

Category

Treatment - Drugs

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Description

Control group: In the second group, a ringer solution will be used to prepare the cardiopulmonary bypass system. Also, the venofundin 6% etherified starch solution at 15 cc / kg body weight, heparin 3 units per ml of prime solution, sodium bicarbonate at 24 mEq / l of prime solution and Mannitol 0.5 grams per kilogram of

body weight will be added. In the case of low hematocrit, packed cell will also be used. The amount of Ringer's solution will be about 350-400 cc and once at the start of the bypass. Ringer's solution is the product of Iranian Pharmaceutical & Parenteral Products factory and made in Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room of Shahid Rajaei Cardiovascular Center Tehran

Full name of responsible person

Davood Samiei

Street address

Ayatollah Hashemi Rafsanjani Highway. cross Vali-Asr Ave.

City

Tehran

Province

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Postal code

19956114331

Phone

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Email

samdvd1979@yahoo.com

Web page address

<http://rhc.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Rajaei Cardiovascular Center Tehran

Full name of responsible person

دکتر مازیار غلامپور

Street address

Highway Ayatollah Hashemi Rafsanjani Exp, cross Valiasr St

City

Tehran

Province

Tehran

Postal code

19956114331

Phone

+98 21 2392

Email

drgholampour@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Rajaee Cardiovascular Center Tehran

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

City

Tehran

Province

Tehran

Postal code

19956114331

Phone

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Email

samdvd1979@yahoo.com

Web page address<http://rhc.ac.ir/>**Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Rajaee Cardiovascular Center

Full name of responsible person

Davood Samiei

Position

Perfusionist

Latest degree

Master

Other areas of specialty/work

Perfusionist

Street address

Ayattollah Hashemi Highway, cross Vali-asr Ave. Shahid Rajai Cardiovascular, Medical and Research Heart Center

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Shahid Rajai Heart Center

Full name of responsible person

Davood Samiei

Position

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Latest degree

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Other areas of specialty/work

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Shahid Rajai Cardiovascular Center

Full name of responsible person

Davood Samiei

Position

Perfusionist

Latest degree

Master

Other areas of specialty/work

Perfusion

Street address

Ayattollah Hashemi Highway, cross Vali-asr Ave. Shahid Rajai Cardiovascular, Medical and Research Heart Center

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

Patient privacy

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available