Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of citrate-phosphate-Dextrose Solution on reperfusion Injury in Coronary Artery Bypass

Protocol summary

Summary

During a year patients whom undergoing elective coronary artery bypass surgery in Madani educational heart center in Tabriz, according our inclusion criteria that having satisfied were enrolled in this study. And then randomly were divided to one of the study or control groups. And matched together according to sex, age and NYHA class. Inclusion criteria were; not having another heart attack or another heart surgery at same time; no previous heart surgery; positive history of past severe disease; on-emergency surgery; the absence of high risk surgery; to abandon cases involving one vessel; uncontrolled diabetes; lack of severe left ventricular dysfunction; no MI with Q wave in 6 past weeks; lack of severe lesions of LM (greater than equal to 50%); unstable angina; non-cytotoxic drugs and radiation use; no recent blood transfusion in past month and willingness to participate in the study; Exiting criteria were; the operation of the on pump switch to off pump; addition of other surgery such as surgery aneurysmectomy LV; performed endarterctomy on the involved vessels ;prolonged clamping more than 100 minutes; prolonged pump more than 130 minutes; hemolysis of samples obtained from patients; clotting of samples taken from patients; lack of proper storage and transport of samples at the usual time; less than 5 / 1 cc of blood serum sample size.. Objectives of this study was to determined of the impact of citrate phosphate dextrose (CPD) solution at the end of cardiopulmonary bypass (CPB) on left ventricular ejection fraction (EF) and on antioxidants superoxide dismutase, malondialdehyde total antioxidant capacity in patients after coronary artery bypass graft surgery. This is double blind cross-sectional study. Random list reserve and hidden beside perfusionist who was responsible of injection of citrate phosphate dextrose solution at the end of cardiopulmonary bypass. The patients were anesthetized during surgery and were not aware of citrate phosphate dextrose solution injection or infusion at the end of the pump. The surgeon and cardiologist who measured of ejection fraction before and after the operation and administration of the laboratory were not informed about the injection or not injection of citrate phosphate dextrose solution during surgery. The number of sample size based on other studies has been determined 50. Before the surgery all of the patients in both groups were inform about the benefits of this research and then if they signed the consent form will continue in the study. Patients were assured that any time they can come out of research. In case group after surgery and before the opening of the aortic clamping, warm blood shot of citrate phosphate dextrose solution (3cc to 100 cc) amount of (100 cc/min/m2BSA) was injected for three minutes, until perfusion pressure maintaining of 30 mmHg. After the ending of warm blood shot injection, calculating the net blood pressure amount 50 to75 mmHg until the heart rate (7 to 10 minutes) continued. In control group only injected pure blood. Blood samples (10 cc for each time) were measured respectively for measurement of cardiac enzymes and inflammatory factors in before opening the bypass, before clamping and 10 minutes after opening the clamping of the coronary sinus and venous blood, and also when patient's arrival in ICU and the first and also second morning after surgery was taken only from vein. Main outcomes measure variables are: Measurement of serum malondialdehyde (MDA): Total Antioxidant Capacity and superoxide dismutase (SOD). Main outcomes measure variables are: Measurement of serum malondialdehyde (MDA): Total Antioxidant Capacity and superoxide dismutase (SOD).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108147325N1**
Registration date: **2011-09-17, 1390/06/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2011-09-17, 1390/06/26

Registrant information
Name
Alireza Yaghoubi
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Tabriz university of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Tabriz university of medical science.

Expected recruitment start date
2011-02-20, 1389/12/01

Expected recruitment end date
2011-06-22, 1390/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of citrate-phosphate-Dextrose Solution on reperfusion Injury in Coronary Artery Bypass

Public title
Effect of citrate-phosphate-Dextrose Solution on reperfusion Injury in Coronary Artery Bypass Surgical Patient Undergoing Cardiopulmonary Bypass

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria were; not having another heart attack or another heart surgery at same time; no previous heart surgery; positive history of past severe disease; on-emergency surgery; the absence of high risk surgery; to abandon cases involving one vessel; uncontrolled diabetes; lack of severe left ventricular dysfunction; no MI with Q wave in 6 past weeks; lack of severe lesions of LM (greater than equal to 50%); unstable angina; non-cytotoxic drugs and radiation use; no recent blood transfusion in past month and willingness to participate in the study; Exiting criteria were; the operation of the on pump switch to off pump; addition of other surgery such as surgery aneurysmectomy LV; performed endarterctomy on the involved vessels ;prolonged clamping more than 100 minutes; prolonged pump more than 130 minutes; hemolysis of samples obtained from patients; clotting of samples taken from patients; lack of proper storage and transport of samples at the usual time; less than 5 / 1 cc of blood serum sample size..

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
After selecting the group of patients from on pump and off pump; according to the considerations on the status of involved vessels anatomic; with renal disease; cerebrovascular disease; a history of stroke; severe ascending aorta atherosclerosis relatively severe carotid artery stenosis; study continued.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Golgasht Street, Tabriz University of Medical Sciences, Vice Chancellor, Tabriz _Iran.
City
Tabriz
Postal code
Iran

Approval date
2010-12-06, 1389/09/15

Ethics committee reference number
5.4.7354

Health conditions studied

1

Description of health condition studied
cardiac

ICD-10 code
T82.7

ICD-10 code description

Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts

Primary outcomes

1

Description

Measurement of cardiac enzymes and inflammatory factors

Timepoint

Oxidative stress markers in 5 stage and cardiac enzymes in 3 stage of surgery measured.

Method of measurement

10 cc of blood was taken in , before the bypass ,before opening the clamping, opening 10 minutes after clamping from the coronary sinus , first day and second day after surgery from venous blood .

Secondary outcomes

1

Description

Total serum antioxidant

Timepoint

Before ischemia and after reperfusion

Method of measurement

Total antioxidant capacity in serum using a commercial kit Ltd Randox Laboratories UK, CatNo.NX2332 were measured.

Intervention groups

1

Description

The control group was injected only pure blood. But all routine procedures were performed for them. Blood samples (10 cc for each time) were measured respectively for measurement of cardiac enzymes and inflammatory factors in before opening the bypass, before clamping and 10 minutes after opening the clamping of the coronary sinus and venous blood, and also when patients arrival in ICU and the first and second morning after surgery was taken only from vein.

Category

Treatment - Drugs

2

Description

Before the surgery all of the patients in both groups were inform about the benefits of this research and then, if they signed the consent form, will entrance to the study. Patients were assured that, they can come out of research any time. The patients were anesthetized during surgery and were not aware of citrate phosphate dextrose solution injection or infusion at the end of the pump. The surgeon and cardiologist who measured of ejection fraction before and after the operation and administration of the laboratory were not informed about the injection or not injection of citrate phosphate dextrose solution during surgery. In case group after surgery and before the opening of the aortic clamping, warm blood shot of citrate phosphate dextrose solution (3cc to 100 cc) amount of (100 cc/min/m2BSA) was injected for three minutes, until perfusion pressure maintaining of 30 mmHg. After the ending of warm blood shot injection, calculating the net blood pressure amount 50 to75 mmHg until the heart rate (7 to 10 minutes) continued. In control group only injected pure blood. Blood samples (10 cc for each time) were measured respectively for measurement of cardiac enzymes and inflammatory factors in before opening the bypass, before clamping and 10 minutes after opening the clamping of the coronary sinus and venous blood, and also when patient's arrival in ICU and the first and second morning after surgery was taken only from vein.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Madani Heart Center

Full name of responsible person

Dr Alireza Yaghoubi

Street address

Golgasht Street, Cardiovascular research center, Madani Heart Center, Tabriz, Iran.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor, Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohamadreza Rashidy

Street address

Golgasht Street, , Vice Chancellor, Tabriz University of Medical Sciences, Tabriz _Iran.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Alireza Yaghoubi

Position

Cardiovascular surgeon, Chancellor of Tabriz University of Medical Sciences.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty