Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Effect of Remote Ischemic Preconditioning on the Incidence of Acute Kidney Injury in Patients Undergoing Coronary Artery Bypass Graft Surgery: A Randomized Controlled Trial

Protocol summary

Summary

Acute kidney injury (AKI), a common and serious complication of coronary artery bypass graft (CABG) surgery with cardiopulmonary bypass (CPB), is associated with inflammatory reactions and ischemia-reperfusion injury. Remote ischemic preconditioning (RIPC) which is transient ischemia and reperfusion of a limb, is reported to reduce the risk of CPB-associated myocardial and acute kidney injury, but uncertainty remains. In this prospective, double-blind, randomized, controlled trial at the Namazi and Shahid Faghihi hospitals, Shiraz, Iran, 177 adult patients undergoing elective or urgent on-pump CABG surgery will be randomly assigned to either RIPC group (n=90) or control group (n=90). The patients in RIPC group will receive three cycles of 5 min ischemia and 5 min reperfusion in the upper arm after induction of anesthesia. We will place an uninflated cuff on the arm for 30 min in the control group. The primary end point is the incidence of acute kidney injury defined as an elevation of serum creatinine of ≥0.3 mg/dl or ≥50% within 72 h after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017110537254N1**
Registration date: **2017-11-09, 1396/08/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-09, 1396/08/18

Registrant information

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Sina Bagheri
Name of organization / entity
Shiraz Nephro Urology Research Center
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Recruitment status

Recruitment complete

Funding source

Vice chancellery for research affairs, Shiraz University of Medical Sciences

Expected recruitment start date

2013-11-02, 1392/08/11

Expected recruitment end date

2017-02-04, 1395/11/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Remote Ischemic Preconditioning on the Incidence of Acute Kidney Injury in Patients Undergoing Coronary Artery Bypass Graft Surgery: A Randomized Controlled Trial

Public title

Effect of Remote Ischemic Preconditioning on the Incidence of Acute Kidney Injury in Patients Undergoing Coronary Artery Bypass Graft Surgery

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: • Candidate cardiac surgical patients • Elective or urgent on pump coronary artery bypass grafting (CABG) • Age 18 to 85 years • Signed informed consent Exclusion Criteria: • End-stage renal disease (receiving hemodialysis or glomerular filtration rate <15 ml/min/1.73m2) • Peripheral vascular disease • Severe hepatic disease • Planned off-pump surgery • Pregnancy

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
clinicaltrials.gov

Secondary trial Id
NCT02981680

Registration date
2016-12-05, 1395/09/15

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand Blvd.

City
Shiraz

Postal code

Approval date
2017-01-23, 1395/11/04

Ethics committee reference number
IR.SUMS.MED.REC.1395.61

Health conditions studied

1

Description of health condition studied
Acute kidney injury

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Remote ischemic preconditioning

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Coronary artery bypass graft surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Incidence of postoperative acute kidney injury (AKI)

Timepoint
Within the first 72 hours after surgery

Method of measurement
Defined as an elevation of serum creatinine of ≥0.3 mg/dl or ≥50% within 72 hours after surgery

Secondary outcomes

1

Description
Duration of hospital stay

Timepoint
Through hospital stay after surgery

Method of measurement
in days

2

Description
Duration of ICU stay

Timepoint
Through ICU stay

Method of measurement
in days

3

Description
All cause mortality

Timepoint
Through hospital stay after surgery

Method of measurement

number of observed cases

4

Description
requiring hemodialysis
Timepoint
Through hospital stay after surgery
Method of measurement
number of observed cases

5

Description
Postoperative liver function
Timepoint
Preoperatively and at 24 h post-surgery
Method of measurement
By measuring serum AST, ALT, T.bilirubin, and albumin

6

Description
Incidence of postoperative atrial fibrillation (AF)
Timepoint
Within the first 72 hours after surgery
Method of measurement
Defined as the incidence of new-onset AF lasting for five minutes or longer

7

Description
Incidence of postoperative stroke
Timepoint
Through hospital stay after surgery
Method of measurement
Defined as a new ischemic or hemorrhagic cerebrovascular accident with neurological deficit lasting >24 h

Intervention groups

1

Description
Intervention: RIPC Patients in the remote ischemic preconditioning (RIPC) group will receive three sequential sphygmomanometer cuff inflations on their right upper arm after induction of anesthesia in the operating room. The cuff will be inflated by the OR nurse up to 200 mmHg for five minutes each occasion, with five minutes deflation in between inflations. Following this pre-conditioning phase, surgery will be started. The entire pre-conditioning phase will last 30 minutes.
Category
Prevention

2

Description
Control: sham-RIPC Patients in the sham-RIPC group will have the sphygmomanometer cuff placed on their right upper arm, but the cuff will not be inflated. Similar to patients in the RIPC group, patients in the sham-RIPC group will undergo the same 30 minute delay before starting surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namzi Hospital
Full name of responsible person
Street address
City
Shiraz

2

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellery for research affairs, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Shiraz University of Medical Sciences, Zand Blvd.
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellery for research affairs, Shiraz 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
Shiraz nephro-urology research center

Full name of responsible person
Sina Bagheri

Position
M.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

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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