Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of remote ischemic preconditioning in prevention of delirium in patient with cardiopulmonary bypass

Protocol summary

Summary

Purpose of study: Determining the effect of remote Ischemic preconditioning in prevention of delirium in patients with coronary artery bypass graft. Study design: Randomized, non-blind Sample size: 80 Major inclusion criteria: candidates for elective cardiopulmonary bypass surgery; 55-70 years old patients؛ patients with EF greater than 35% (Severe LV dysfunction). Major exclusion criteria: Reexploration (Patients who return to operating room after heart surgery due to excessive bleeding)؛ embedded IABP (embedded balloon pump in the operating room or the ICU because of LV dysfunction؛ patients with acute MI (patients with myocardial infarction during previous week)؛ DM؛ history of stroke؛ upper extremity peripheral vascular problems؛ unwillingness to continue the participation, no initial consent؛ transfer to other medical centers؛ psychiatric drugs؛ history of psychiatric disorders such as psychosis, mental retardation؛ presence of ST changes during operation. Intervention: a questionnaire (include the checklist for surveying psychological status of patient) is provided. The night before open heart surgery, delirium questionnaire will be filled. Then intervention method called remote preconditioning Ischemic will be used as follow: Remote preconditioning Ischemic will be applied after induction of anesthesia using a inflated blood pressure cuff, 9-12 cm wide, closed at the top of participants arm.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041712830N21**
Registration date: **2017-06-29, 1396/04/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-29, 1396/04/08

Registrant information

Name
Faezeh Jahanpour
Name of organization / entity
Bushehr University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Bushehr University Of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of remote ischemic preconditioning in prevention of delirium in patient with cardiopulmonary bypass

Public title

The effect of remote ischemic preconditioning in prevention of delirium in patient with cardiopulmonary bypass

Purpose

Prevention

Inclusion/Exclusion criteria

Major inclusion criteria: candidates for elective cardiopulmonary bypass surgery; 55-70 years old patients؛ patients with EF greater than 35% (Severe LV dysfunction). Major exclusion criteria: Reexploration (Patients who return to operating room after heart surgery due to excessive bleeding)؛ embedded IABP (embedded balloon pump in the operating room or the ICU because of LV dysfunction؛ patients with acute MI (patients with myocardial infarction during previous week)؛ DM؛ history of stroke؛ upper extremity peripheral vascular problems؛ unwillingness to continue the participation, no initial consent؛ transfer to other medical centers؛ psychiatric drugs؛ history of psychiatric disorders such as psychosis, mental retardation؛ presence of ST changes during operation

Age

From **55 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Randomization by using Excel table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

Street address

Bushehr University Of Medical Sciences, Next to the hospital Salman Farsi, Sabzabad,Bushehr

City

Bushehr

Postal code

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

IR.BPUMS.REC.1395.210

Health conditions studied

1

Description of health condition studied

delirium

ICD-10 code

F05

ICD-10 code description

Postoperative delirium

Primary outcomes

1

Description

Delirium

Timepoint

Before the intervention, one to five days after the intervention

Method of measurement

The checklist of delirium(NEECHAM)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A checklist that investigates the psychological status of patients will be filled the night before open heart surgery. The occurrence of delirium is investigated by questionnaire from the night before surgery daily until 5 days after the operation. Assessing delirium will be done in 18-20 pm. The type, dosage and time of using medication (for example haloperidol if necessary) will also be recorded in the questionnaire. In remote ischemic preconditioning technique, an inflated blood pressure cuff, 9-12 cm wide, will be used after induction of anesthesia which will be closed at the top of participants’arm. Pressure of cuff is 200 mm Hg. Duration of use of inflated cuff is five minutes and after that cuff will be emptied in five minutes. The intervention will be done in three five-minute cycles and totally takes 30 minutes. During the anesthesia induction phase, medications such as Etomidate, which cannot induce remote preconditioning ischemic condition, will be used . After ECG, SPO2 and arterial line monitoring, induction of anesthesia starts. The method of anesthesia induction is considered by medications including Etomidate + Sufentanil+Midazolam. After intubating and placing CVP, patients are maintained by removal of inhaled medications Isoflurane and Sevoflurane and application of infusion of Sufentanil + Midazolam+ Atracurium. All patients receive 100% oxygen during anesthesia step. In anesthesia, patients candidate for open heart surgery require embedded arterial line (mostly from the left hand which induces no cardiovascular problems) and intravenous lines are inserted in the other hand. Cuff will

be closed on another hand. All intravenous lines will be taken in the same hand with arterial lines. This intervention will be done under supervision of heart anesthesiologist.

Category

Prevention

2

Description

Control Group: In this group, alsothe questionnaire in the night before surgery and daily to 5 days after surgery would be filled. In this group, after induction of anesthetic, preconditioning Ischemic method wouldn't be used. The method and the use of anesthetic drugs in this group is similar to intervention group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Boshehr Heart Center hospital

Full name of responsible person

Dr Hajyoni

Street address

Boshehr Heart Center hospital, Crossroads of Justice, Sangi street

City

boshehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Bushehr University of Medical Sciences

Full name of responsible person

dr Afshin Ostovar

Street address

Bushehr University Of Medical Sciences

City

Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Bushehr 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

Bushehr University of Medical Sciences

Full name of responsible person

Dr Faezeh Jahanpour

Position

PhD in nursing/ Faculty member

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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