

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of pulsatile and non-pulsatile blood flow on cerebral oximetry in patients with different intensities of carotid stenosis and without stenosis during coronary artery bypass graft (CABG)

Protocol summary

Study aim

Determining the effect of pulsatile and non-pulsatile blood flow on cerebral oximetry during CPB in patients with carotid stenosis below 50%, 50-70% and without stenosis. Comparison of the effect of pulsatile and non-pulsatile flow in 3 groups on cerebral oximetry during CABG.

Design

Non-randomized crossover clinical trial (same interventions in all individuals)

Settings and conduct

This study will be performed on patients with CABG surgery who refer to Isfahan Chamran Heart Center. The severity of carotid stenosis will be determined by Carotid Doppler and the conditions for inclusion or non-inclusion will be measured. Method of intervention: after the start of cardiopulmonary bypass; 15 minutes after aortic cross clamp, blood flow changes from non-pulsatile to pulsatile for 15 minutes. The patient's cerebral oximetry is measured by NIRS after aortic clamp, immediately before the start of pulsatile flow, 15 minute after the start of pulsatile flow, and after return to non-pulsatile flow. Finally, the data will be statistically analyzed and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: CABG Elective surgical patients With carotid stenosis under 70% and without carotid stenosis
Non-Inclusion criteria: No recent stroke No vertebral artery stenosis

Intervention groups

After dividing the participants into 3 groups with carotid stenosis below 50%, 50-70% and without stenosis; 2 interventions in all participants will be done. At the start of the CABG surgery, the blood flow by the CPB machine will be non-pulsatile and then after 15 minutes of aortic cross-clamp, the flow was changed by the CPB machine to a pulsatile mode about 15 minutes to record the

changes in cerebral oximetry by the NIRS.

Main outcome variables

Cerebral oximetry (Cerebral oxygen saturation) during pulsatile and non-pulsatile blood flow

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170620034666N4**

Registration date: **2022-01-30, 1400/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-30, 1400/11/10**

Update count: **0**

Registration date

2022-01-30, 1400/11/10

Registrant information

Name

Mehran Shahzamani

Name of organization / entity

Isfahan university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 31 3670 1227

Email address

m.shahzamani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of pulsatile and non-pulsatile blood flow on cerebral oximetry in patients with different intensities of carotid stenosis and without stenosis during coronary artery bypass graft (CABG)

Public title

Comparative study of pulsatile and non-pulsatile blood flow on cerebral oximetry in patients with different intensities of carotid stenosis and without stenosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Elective CABG surgery patients With carotid stenosis below 70% and without carotid stenosis

Exclusion criteria:

Recent stroke Vertebral artery stenosis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 61

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Ave, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-11-22, 1400/09/01

Ethics committee reference number

IR.MUI.MED.REC.1400.645

Health conditions studied**1****Description of health condition studied**

Coronary artery bypass graft

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes**1****Description**

Cerebral oximetry

Timepoint

After aortic cross clamp, immediately before the start of the pulsatile blood flow, 15 minutes after the start of the pulsatile flow (end of the pulsatile flow) and after returning to the non-pulsatile flow

Method of measurement

By near infrared spectroscopy device monitor

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Nonpulsatil blood flow: From the start of cardiopulmonary bypass during CABG surgery, the blood flow carried by the cardiopulmonary bypass machine to the body will be nonpulsatil mode in all participants and their cerebral oxygen saturation will be recorded by the near-infrared spectroscopy (NIRS) device leads.

Category

Treatment - Surgery

2**Description**

Intervention group: Pusatil blood flo: After some times of aortic cross clamping during surgery (15-20 minutes after the start of aortic cross clamping) we will change the blood flow from nonpulsatil (linear) to pulsatile blood flow for 15 minutes by cardiopulmonary bypass machine

in all participants and its effects on cerebral oxygen saturation will be recorded during this 15 minutes by the leads of the Near Infrared Spectroscopy (NIRS).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Heart Center of Isfahan

Full name of responsible person

Mehran Shahzamani

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3rd Moshtagh st, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

research department of Isfahan university of medical sciences

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abdollahzade205@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mehran Shahzamani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

After finishing the study the data will be available

When the data will become available and for how long

After publishing the article

To whom data/document is available

Faculty members

Under which criteria data/document could be used

Contacting the scientist responsible by email causes the data to be used in order to use the data in scientific research such as meta analysis or secondary analysis

From where data/document is obtainable

Scientific responsible can provide the study data to academic researchers without the name of individuals. Scientific responsible: Dr.mehran shahzamani. Address: Isfahan. Moshtagh Ave, chanran heart center. postal code: (8174673461). Call number: (+98 31 3670 1227). Mobile phone number: (+98 913 123 1453). Email: m.shahzamani@med.mui.ac.ir

What processes are involved for a request to access data/document

Just forwarding email to scientific responsible of this trial is enough. Email address: m.shahzamani@med.mui.ac.ir (Will be answered within a month.)

Comments