Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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
Isfehan
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
Street address
3rd Moshtagh st, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3260 0961
Email
m.shahzamani@med.mui.ac.ir

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 scienes
Street address
hezarjarib blvd, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
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
Street address
Isfahan, Hezarjarib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3670 1227
Email
m.shahzamani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
مهران شاهزمانی
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Isfahan, Hezarjarib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 913 123 1453
Email
m.shahzamani@med.mui.ac.ir

Person responsible for updating data

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

Street address
Isfahan, Hezarjarib Ave

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3670 1227

Email
m.shahzamani@med.mui.ac.ir

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