Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intravenous vitamin C infusion and evaluation of brain oxygenation with a cerebral oximetry in improving brain perfusion of diabetic patients during general anesthesia in vascular surgery

Protocol summary

Study aim

The effect of intravenous vitamin C infusion and evaluation of brain oxygenation with cerebral oximetry in improving brain perfusion of diabetic patients during general anesthesia in carotid endarterectomy surgery

Design

This phases 3 clinical trial has a control group, with parallel groups, double-blind, randomized, on 50 patients, which are completely randomized by the method of block randomization in the form of quadruple blocks and non-blind, divide into two groups of vitamin C and placebo.

Settings and conduct

For patients' candidates for vascular surgery under general anesthesia referred to Ayatollah Taleghani Hospital in Tehran, a cerebral oximeter sensor is placed on both sides of the patient's forehead and continuous oxygenation measurement is started. The patient is placed in the supine position for 10 minutes. Before and after induction of anesthesia and at the end of the operation, heart rate, blood sugar, mean arterial blood pressure, oxygen saturation of brain tissue (rSO2, SpO2, PaCo2, ScO2, EtCO2) are measured.

Participants/Inclusion and exclusion criteria

Diabetic patients who are candidates for carotid endarterectomy under general anesthesia with the consent to participate in the project, age 50 years and older, ASA Class II are included in the study. Patients with dissatisfaction with participation in the plan, ASA class III and above, hemoglobin level less than 8 g/dl, brain failure, metabolic disease, and any type of intracranial pathology are excluded.

Intervention groups

Placebo group: they will receive an infusion of 500 ml isotonic saline, half an hour before induction of anesthesia. Vitamin C group: They will receive an infusion of 1 gr of vitamin C diluted in 500 ml of isotonic saline, half an hour before induction of anesthesia.

Main outcome variables

rSO; SpO2; PaCo2; ScO2; EtCO2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210830052345N1**
Registration date: **2021-09-23, 1400/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-23, 1400/07/01**
Update count: **0**

Registration date

2021-09-23, 1400/07/01

Registrant information

Name

Navid Tavakoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2282 4929

Email address

navidtavakoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-05, 1400/06/14

Expected recruitment end date

2021-10-21, 1400/07/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of intravenous vitamin C infusion and evaluation of brain oxygenation with a cerebral oximetry in improving brain perfusion of diabetic patients during general anesthesia in vascular surgery

Public title
The effect of intravenous vitamin C infusion on improvement of cerebral blood flow of diabetic patients and evaluation of brain oxygenation with a cerebral oximeter during general anesthesia in vascular surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic patients who are candidates for vascular surgery Having the consent to participate in the project Age 50 years and older ASA Class II
Exclusion criteria:
Patients with dissatisfaction with participation in the plan ASA class III and above Hemoglobin level less than 8 g/dl Brain failure Metabolic disease Any type of intracranial pathology
Age
From **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the restricted randomization method from type of block randomization. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. The size of all blocks is equal, and we will have 4 groups of 4 blocks (including 2 participants in the intervention group and 2 participants in the control group) in this two-group experiment. Randomization tool also uses random allocation software that these random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants who were willing to participate in the project, as well as the clinical caregiver who was in charge of drug or placebo infusion and patient care, were blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Third Floor, School of Medicine, Shahid Arabi St., Yemen St., Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2019-05-14, 1398/02/24
Ethics committee reference number
IR.SBMU.MSP.REC.1398.167

Health conditions studied

1

Description of health condition studied
Vascular surgery (carotid endarterectomy)
ICD-10 code
G46
ICD-10 code description
Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description
Blood pressure
Timepoint
Before and after Anesthesia induction and measurement at the end of the operation
Method of measurement
Barometer (Non-Invasive Blood Pressure)

2

Description
Heart rate

Timepoint
Before and after Anesthesia induction and measurement at the end of the operation
Method of measurement
Cardiac monitoring

3

Description
Blood sugar
Timepoint
Before and after Anesthesia induction and measurement at the end of the operation
Method of measurement
Glucometer

4

Description
EtCO2
Timepoint
Before and after Anesthesia induction and measurement at the end of the operation
Method of measurement
Cerebral oximetry

5

Description
rSO2
Timepoint
Before and after Anesthesia induction and measurement at the end of the operation
Method of measurement
Cerebral oximetry

6

Description
ScO2
Timepoint
Before and after Anesthesia induction and measurement at the end of the operation
Method of measurement
Cerebral oximetry

7

Description
SpO2
Timepoint
Before and after Anesthesia induction and measurement at the end of the operation
Method of measurement
Pulse oximetry

8

Description
PaCo2
Timepoint
Before and after Anesthesia induction and measurement at the end of the operation
Method of measurement
Cerebral oximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group or vitamin C: They will receive an infusion of 1 gr of vitamin C diluted in 500 ml of isotonic saline, half an hour before induction of anesthesia
Category
Treatment - Surgery

2

Description
Control group or placebo: They will receive an infusion of 500 ml isotonic saline, half an hour before induction of anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Medical and Educational Center
Full name of responsible person
Navid Tavakoli
Street address
Ayatollah Taleghani Hospital, Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Navid Tavakoli
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Navid Tavakoli
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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