

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

rSO₂; 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

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2303 1111

Email

taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Navid Tavakoli

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 23871

Email
info@sbmu.ac.ir

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

Street address
Unit 5, No. 2 , Yazdan Alley, Nastaran St., after Ajudanieh crossroad, Aqdasiyeh St.

City
Tehran

Province
Tehran

Postal code
1957665353

Phone
+98 21 2282 4929

Email
navidtavakoli@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Navid Tavakoli

Position
Resident

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Tehran

Postal code
1957665353

Phone
+98 21 2282 4929

Email
navidtavakoli@sbmu.ac.ir

Person responsible for updating data

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

Street address
Unit 5, No. 2 , Yazdan Alley, Nastaran St., after Ajudanieh crossroad, Aqdasiyeh St. ,Tehran,Tehran

City
Tehran

Province
Tehran

Postal code
1957665353

Phone
+98 21 2282 4929

Fax

Email
Navidtavakoli@sbmu.ac.ir

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