

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of Acute Normovolemic Hemodilution(ANH) on hemodynamics and blood transfusion rate in patients undergoing on-pump CABG

Protocol summary

Study aim

Acute Normovolemic Hemodilution (ANH) is one of the effective methods to reduce the need for allogeneic blood transfusion, and its positive effects have been proven in various studies.

Design

Patients are divided into two groups by simple random sampling based on the case number and table of random numbers. A double-blinded control clinical trial is performed on 172 patients.

Settings and conduct

All the procedures and data recording are done in the operation room. The study is designed to be double-blinded, the analyzer and the patients are blind. The professor performs all procedures, and the anesthesiologist's assistant records the data. The patient is unaware of being in the study group.

Participants/Inclusion and exclusion criteria

CABG candidates with Hemoglobin levels above 14 g/dL and Left Ventricular Ejection Fraction above 35% will be interviewed to participate in our study.

Intervention groups

1. in the intervention group, after explaining the steps of the study, and obtaining the patient's consent to participate in the study, after induction of anesthesia, CV-line, and arterial line insertion, a unit of blood is taken from the patient through an arterial catheter in the standard bag of the blood transfusion organization. In some patients with Hb levels above 16, two units of blood are going to be taken. Each 1 cc of blood will be replaced with 3 ccs of intravascular normal saline. 2. In control group after obtaining patient's consent, induction of anesthesia, CV-line and Arterial line insertion, without drawing any blood, we will proceed to surgery.

Main outcome variables

The need for blood transfusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180603039966N2**

Registration date: **2022-11-12, 1401/08/21**

Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**

Update count: **0**

Registration date

2022-11-12, 1401/08/21

Registrant information

Name

Sina Hasannasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3235 2508

Email address

sina.hasannasab@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Acute Normovolemic Hemodilution (ANH) on hemodynamics and blood transfusion rate in patients undergoing on-pump CABG

Public title

ANH effect on hemodynamic and blood transfusion rate in CABG patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

CABG candidates with hemoglobin level above 14 g/dL
CABG candidates with left Ventricular Ejection Fraction above 35%

Exclusion criteria:

Patients refusal to participate
History of cerebrovascular accident (ischemic or hemorrhagic)
History of carotid stenosis
History of ischemia or active bleeding (GI bleeding, mesenteric ischemia, claudication)
History of renal failure
History of liver failure

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **172**
More than 1 sample in each individual
Number of samples in each individual: **86**
Patients who are admitted to Amir-al-Momenin hospital in Kordkoy and Baqiyatallah hospital in Tehran for elective CABG are evaluated to participate in the study.

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the table of random numbers, a column is randomly selected and choose the right side column, If the last digit of the number selected is the same as the patient's last digit case number, the patient will be in the intervention group, and otherwise in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The professor does all the procedures and the data is recorded by the anesthesia technician. The data analyzer does the analysis based on groups A and B. The patient is anesthetized during the entire surgery and procedure and unaware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Glestan Medical University Ethics Committee

Street address

shastkola road

City

Gorgan

Province

Golestan

Postal code

4916694667

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.GOUMS.REC.1401.002

Health conditions studied

1

Description of health condition studied

Patients undergoing On-Pump CABG

ICD-10 code

I25.70

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris

Primary outcomes

1

Description

Need for blood transfusion

Timepoint

Will be recorded during surgery and until the discharge from the ICU.

Method of measurement

Number of packed cell transfused

Secondary outcomes

1

Description

Mean Arterial Pressure (MAP)

Timepoint

Will be recorded during surgery and also at 0, 6, 12, 24 hours after the surgery, And if necessary, will be assessed PRN

Method of measurement

Transducer via Arterial line catheter

2

Description

Systolic Blood Pressure(SBP)

Timepoint

Will be recorded during surgery and also at 0, 6, 12, 24 hours after the surgery, And if necessary, will be assessed PRN

Method of measurement

Transducer via Arterial line catheter

3

Description

Diastolic Blood Pressure(DBP)

Timepoint

Will be recorded during surgery and also at 0, 6, 12, 24 hours after the surgery, And if necessary, will be assessed PRN

Method of measurement

Transducer via Arterial line catheter

4

Description

Urine Output(U/O)

Timepoint

Will be recorded during surgery and also at 0, 6, 12, 24 hours after the surgery, And if necessary, will be assessed PRN

Method of measurement

Urinary drainage Bag

5

Description

Central Vein Pressure

Timepoint

Will be recorded during surgery and also at 0, 6, 12, 24 hours after the surgery, And if necessary, will be assessed PRN

Method of measurement

CVP Manometer set

6

Description

Arterial Blood PH

Timepoint

Will be recorded during surgery and also at 0, 6, 12, 24 hours after the surgery, And if necessary, will be assessed PRN

Method of measurement

ABG Analyzer

7

Description

Partial pressure of oxygen(Pao2)

Timepoint

Will be recorded during surgery and also at 0, 6, 12, 24 hours after the surgery, And if necessary, will be assessed PRN

Method of measurement

ABG Analyzer

8

Description

Partial pressure of carbon dioxide (PaCO2)

Timepoint

Will be recorded during surgery and also at 0, 6, 12, 24 hours after the surgery, And if necessary, will be assessed PRN

Method of measurement

ABG Analyzer

Intervention groups

1

Description

Intervention group: Patients who are admitted to Amir-al-Momenin hospital in Kordkoy and Baqiyatallah hospital in Tehran for elective CABG who undergoes Acute Normovolemic Hemodilution. Every 1cc of blood taken from the patient's arterial catheter is compensated with 3cc of intravenous normal saline, the parameters are measured, and the stored blood is injected into the patient at the end of the surgery.

Category

Treatment - Other

2

Description

Control group: Intervention group: Patients who are admitted to Amir-al-Momenin hospital in Kordkoy and Baqiyatallah hospital in Tehran for elective CABG who does not undergo Acute Normovolemic Hemodilution. In these patients, an arterial catheter is routinely inserted and hemodynamic parameters are also recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-al-Momenin hospital

Full name of responsible person

Dr. Amirali Jabbari

Street address

Sardar Jangal

City

Kordkoy

Province

Golestan

Postal code

4881899441

Phone

+98 17 3432 5766

Email

h.kordkoy@goums.ac.ir

Web page address

<https://kordkuyheartcenter.goums.ac.ir/>

2

Recruitment center**Name of recruitment center**

Baqiyatallah hospital

Full name of responsible person

Seyyed Mohammad Saeed Ghiasi

Street address

Vanak Square, Mulla Sadra Street, after Sheikh Bahayi

City

Tehran

Province

Tehran

Postal code

141556437

Phone

+98 21 81261

Email

baqhospital@mail.bmsu.ac.ir

Web page address

<https://baq.bmsu.ac.ir/portal/home/>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Amirali Jabbari

Street address

Shast-kola Road, Hirkan blvd

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 2651

Email

Gsm@goums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Amirali Jabbari

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Shast-kola Road, Hirkan blvd

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 2651

Email

dr.a.jabbari@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Amirali Jabbari

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Shast-kola Road, Hirkan blvd

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 2651

Email

dr.a.jabbari@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Sina Hassannasab

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shast-kola Road, Hirkan blvd

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 2651

Email

Drsina.hsn@goums.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