

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the amount of blood transfusion required in candidated patients for radical open prostatectomy by acute normovolemic hemodilution

Protocol summary

Study aim

Determining the possibility of autologous blood transfusion in open radical prostatectomy surgery

Design

A single blind clinical trial including a parallel control group was performed on 30 patients based on referral priority.

Settings and conduct

Patients in need of radical open prostatectomy referred to Hasheminejad Hospital in Tehran will be included in the study if they have the conditions. After anesthesia and complete cardiovascular monitoring, 450 ml of blood is taken from the experimental group. Three times this amount of crystalloid is replaced. In the control group, no intervention is performed. Patients are evaluated at specified times.

Participants/Inclusion and exclusion criteria

Hemoglobin above 12; hematocrit above 30; age 35-80 years old; elective surgery; cardiac output above 45%; ASA class 1 & 2; patient satisfaction. Inclusion criteria of study are no any complications during surgery. Absence of any of the above condition will result to exclusion from the study.

Intervention groups

In this study, in the test group, autologous blood is injected before starting of surgery if required. In the control group, allogeneic blood will be used if needed.

Main outcome variables

Number of autologous blood transfusion; amount of AKI (BUN-Cr) in autologous and allogeneic blood transfusions; variation of hemoglobin, hematocrit, platelet count in autologous and allogeneic blood transfusion; surgeon satisfaction with homeostasis and surgery

General information

Reason for update

Acronym

ANH

IRCT registration information

IRCT registration number: **IRCT20211206053289N1**

Registration date: **2021-12-24, 1400/10/03**

Registration timing: **prospective**

Last update: **2021-12-24, 1400/10/03**

Update count: **0**

Registration date

2021-12-24, 1400/10/03

Registrant information

Name

Fatemeh Aghadjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2245 1623

Email address

f.aghadjani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the amount of blood transfusion required in candidated patients for radical open prostatectomy by acute normovolemic hemodilution

Public title

Comparison of the amount of blood transfusion required in candidate patients for prostatectomy surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hemoglobin will be over than 12 Hematocrit will be over than %30 Elective surgery is considered Age of candidate shall be 35 till 80 years Ejection fraction shall be over than %45 ASA class 1&2 Patient satisfaction

Exclusion criteria:

Liver disease Heart failure Kidney disease Any hematological disease

Age

From **35 years** old to **80 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants are unaware of entering to the test or control groups but the rest of the study team are aware.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Office of Anesthesiology and Intensive Care Group, Building No. 2, Rasoul Akram Hospital, Maziar Mansouri St., Sattar Khan St.

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2020-11-17, 1399/08/27

Ethics committee reference number

IR.IUMS.FMD.REC.1399.562

Health conditions studied

1

Description of health condition studied

Autologous blood transfusion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people who received only autologous blood

Timepoint

During surgery and up to 24 hours later

Method of measurement

Counting the number of blood bags consumed

Secondary outcomes

1

Description

The rate of drop in hemoglobin

Timepoint

24 hours after surgery

Method of measurement

Measurement of hemoglobin level by blood test

Intervention groups

1

Description

Intervention group: From this group of 15 people, 450 ml of blood was taken. It was replaced by 1.5 liters of crystalloid and then surgery was started. During and after the surgery, whenever it was estimated that the patient's bleeding needed to be compensated, autologous blood was injected, and if the bleeding was heavy, allogeneic blood was used.

Category

Treatment - Other

2

Description

Control group: After anesthesia and hemodynamic monitoring in this group of 15 people, surgery was started without any intervention and according to the patient's hemodynamics and the amount of bleeding during surgery, allogeneic blood was injected up to 24 hours later.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Hasheminejad Hospital

Full name of responsible person

Fatemeh Aghadjani

Street address

Shahid Hasheminejad Hospital, Shahid Valinejad Alley, Above Vanak Square, Valiasr St.

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 81161

Email

support@hkc.ir

Web page address

<https://hkc.iums.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motavlian

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research-m@iums.ac.ir

Web page address

<https://vcr.iums.ac.ir/>

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

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Aghadjani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Office of Anesthesiology and Intensive Care Group, Building No. 2, Rasoul Akram Hospital, Maziar Mansouri St., Sattar Khan St.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

f.aghadjani@yahoo.com

Web page address

<https://hrmc.iums.ac.ir/>

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

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Aghadjani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Office of Anesthesiology and Intensive Care Group, Building No. 2, Rasoul Akram Hospital, Maziar

Mansouri St., Sattar Khan St.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 2245 1623

Email

F.ahgadjani@yahoo.com

Web page address

<https://hrmc.iums.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Aghadjani

Position

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Phone

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Email

F.ahgadjani@yahoo.com

Web page address

<https://hrmc.iums.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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All test data of study can be shared after unidentified individuals.

When the data will become available and for how long

Access period will be 6 months after the result publish date

To whom data/document is available

Researchers working in academic, scientific and industrial institutes

Under which criteria data/document could be used

For using in scientific, medical works and for future researches which are working in academic, scientific and industrial institutions, citing the source

From where data/document is obtainable

Dr. Fatemeh Aghadjani Email: f.ahgadjani@yahoo.com
Mobile number: 00989124090068

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

Contact the person mentioned and submit a request with a valid address or e-mail to send data and documentation

Comments