# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**
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/

## 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.ahghadjani@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**