

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effects of testosterone injection in maintaining the stability of blood pressure and hemodynamic parameters of brain dead patients who are candidates for organ donation

#### Protocol summary

##### Study aim

Improving the hemodynamic conditions and blood pressure of patients with minimal inotrope or vasopressor drugs with testosterone injection in brain dead patients who are candidates for organ donation

##### Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 2-3 on 80 patients. Computer-generated random table method was used for randomization

##### Settings and conduct

This double-blind clinical trial will be conducted on 80 male-female brain dead patients who are candidates for organ donation with flank incision at Sina Hospital in Tehran. The patients are divided into two groups by Computer-generated random table. This study is double blind clinical trial. Outcome analyser, the outcome evaluator and the participant are blinded (double blind). Control group patients receive 100 mg of testosterone intramuscularly. Blood pressure the dose of noradrenaline that is infused is checked during hospitalization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: brain dead patients aged 18-60 who are candidates for organ donation. Exclusion criteria: patients who have high blood pressure and do not need inotrope. Hemodynamically unstable patients whose organ donation surgery will be performed in less than 6 hours.

##### Intervention groups

Intervention group: the amount of 100 mg of testosterone is injected into the deltoid muscle at the beginning of the study. Control group: the same amount of placebo drug is injected into the deltoid muscle.

##### Main outcome variables

The amount of vasopressor drugs, systolic blood pressure, diastolic and mean arterial blood pressure,

cardiac output, peripheral vascular resistance, cardiac index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130304012695N17**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

##### Registration date

2023-05-13, 1402/02/23

##### Registrant information

##### Name

mohammadreza khajavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6312 1220

##### Email address

khajavim@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-22, 1402/03/01

##### Expected recruitment end date

2024-04-20, 1403/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effects of testosterone injection in maintaining the stability of blood pressure and hemodynamic parameters of brain dead patients who are candidates for organ donation

**Public title**  
The use of testosterone in brain dead patients who are candidates for organ donation in order to maintain and stabilize blood pressure

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Brain dead patients aged 18-60 years are candidates for organ donation  
**Exclusion criteria:**  
Patients who have high blood pressure and do not need inotropes Hemodynamically unstable patients who will undergo organ donation surgery in less than 6 hours

**Age**  
From **18 years** old to **60 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
For the randomization of patients who meet the inclusion criteria, the method of four blocks including intervention and control groups will be used. The preparation of randomization sequences will be done using the Random Generator software and the created sequences will be given to a trained staff member of the intensive care of unit who is not a member of the research group. The researchers of this study will not be aware of the existing sequences and arrangement of the blocks. After the patient enters the operating room, the trained person removes the first sequence from the special box of this study and according to the predetermined protocol, if it is T, it will be transferred to the intervention group, and if it is C, it will be transferred to the control group.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, patients do not know their group. Eligible participants to receive testosterone (group T) or placebo (group C) are determined according to a computerized randomization program. These drugs are prepared in

syringes and the same volume and are identified with the patient's name and hospital registration number, and in the special care department, these drugs are given to the nurse caring for the patient who is blind to the assigned groups for injection. Another researcher, who is blinded to the assigned groups, will evaluate the hemodynamic status of the patient.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of Sina Hospital

**Street address**

Sina Hospital, Imam Khomeini st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Approval date**

2023-05-09, 1402/02/19

**Ethics committee reference number**

IR.TUMS.SINAHOSPITAL.REC.1402.021

**Health conditions studied**

**1**

**Description of health condition studied**

brain dead

**ICD-10 code**

G96.8

**ICD-10 code description**

Other specified disorders of central nervous system

**Primary outcomes**

**1**

**Description**

Dosage of noradrenaline

**Timepoint**

At the beginning of the patient's entry into the study and 8 hours after drug injection

**Method of measurement**

milliliters per hour

## 2

### **Description**

Peripheral vascular resistance

### **Timepoint**

At the beginning of the patient's entry into the study and 8 hours after drug injection

### **Method of measurement**

By Ultrasonic Cardiac Output Monitor

## **Secondary outcomes**

## 1

### **Description**

Cardiac output

### **Timepoint**

At the beginning of the patient's entry into the study and 8 hours after drug injection

### **Method of measurement**

By Ultrasonic Cardiac Output Monitor

## 2

### **Description**

Cardiac Index

### **Timepoint**

At the beginning of the patient's entry into the study and 8 hours after drug injection

### **Method of measurement**

By Ultrasonic Cardiac Output Monitor

## **Intervention groups**

## 1

### **Description**

Intervention group: 100 mg of testosterone enanthate drug (manufactured by Caspian Tamin Company) was prepared by nurse of the intensive care department according to the grouping of the patient, and after taking a blood sample from the patient, it was injected into the deltoid muscle, the primary variables of the study were recorded and the care routine continues to maintain the patient's hemodynamics, and 8 hours after injection, primary variables will be re-evaluated.

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: The placebo drug that is the same volume as the intervention drug (manufactured by Caspian Tamin Company) was prepared by nurse of the intensive care department according to the grouping of the patient, and after taking a blood sample from the patient, it was injected into the deltoid muscle, the primary variables of the study were recorded and the care routine continues to maintain the patient's hemodynamics, and 8 hours after injection, primary variables will be re-evaluated.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Sina Hospital

#### **Full name of responsible person**

Mohammad Reza Khajavi

#### **Street address**

Sina Hospital Hassan Abad sq, em mam khomini st.

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1136746911

#### **Phone**

+98 21 6634 8555

#### **Fax**

+98 21 6634 8551

#### **Email**

khajavim@tums.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Akbar Fotouhi

#### **Street address**

Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1417653761

#### **Phone**

+98 21 8163 3686

#### **Email**

vcr@tums.ac.ir

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Khajavi

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Sina hospital Hassan Abad Sq, Imam khomeni St,

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 0000

**Fax**

+98 21 6634 8553

**Email**

KHAGAVIM@TUMS.AC.IR

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Khajavi

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Sina hospital Hassan Abad Sq, Imam khomeni St,

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 0000

**Fax**

+98 21 6634 8553

**Email**

khajavim@tums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Khajavi

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Sina hospital ,Hasan Abad Sq, Imam khomeni St,

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 0000

**Fax**

+98 21 6634 8553

**Email**

KHAGAVIM@TUMS.AC.IR

**Web page address**

**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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Main study outcome data

**When the data will become available and for how long**

Six months after the end of the study

**To whom data/document is available**

University researchers

**Under which criteria data/document could be used**

Share experiences to increase the knowledge

**From where data/document is obtainable**

khajavim@tums.ac.ir -Dr.khajavi

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

The request will be made by email and the answer will be given within two months

**Comments**