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 duringhospitalization.

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 routin 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 routin 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.
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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.
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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

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Full name of responsible person

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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