

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of two different doses of mannitol on reducing creatine phosphokinase (CPK) in brain death patients planned for organ donation

Protocol summary

Study aim

Determining the effect of two different doses of mannitol on reducing creatine phosphokinase (CPK) in brain death patients planned for organ donation

Design

A randomized, double-blinding clinical trial, with parallel groups, Phase 2 on 30 patients

Settings and conduct

In this randomized double-blind clinical trial study, 30 eligible patients referred to Al-Zahra Hospital in Isfahan will be included in the study and will be randomly divided into 2 groups. In the two groups, mannitol will be administered at a dose of 0.4 and 0.6 g/kg, respectively. The intervention will be carried out in such a way that the patient's companion and the researcher and statistical analyst will not have any knowledge of the type of intervention. Then the amount of creatine phosphokinase, blood pressure, heart rate, creatinine, sodium and potassium in the blood will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

The criteria for inclusion in the study include patients with brain death, in the age group of 16 to 55 years, with confirmation of the patient's eligibility for kidney donation by the relevant team, the presence of creatine phosphokinase greater than or equal to 5000 units per liter in the initial test of the patient, and the consent of the patient's companions. It is for the purpose of linking and participating in the study. Exclusion criteria include having a pacemaker, cardiac arrest, and sepsis.

Intervention groups

First intervention group: In this group, 0.4 g/kg of mannitol along with 1 mEq of sodium bicarbonate per kilogram will be given in 20 minutes. The second intervention group: In this group, 0.6 g/kg of mannitol along with 1 mEq of sodium bicarbonate per kilogram will be given in 20 minutes.

Main outcome variables

Creatine phosphokinase; Blood pressure; Heart beat; Creatinine; Sodium; Potassium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N67**

Registration date: **2023-05-18, 1402/02/28**

Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**

Update count: **0**

Registration date

2023-05-18, 1402/02/28

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-21, 1402/03/31

Expected recruitment end date

2024-03-21, 1403/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of two different doses of mannitol on reducing creatine phosphokinase (CPK) in brain death patients planned for organ donation

Public title

The effect of two different doses of mannitol on the reduction of creatine phosphokinase in brain death patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirmation of the patient's brain death Having the age of 16 to 55 years Confirmation of the patient's eligibility for kidney donation by the relevant team The presence of creatine phosphokinase greater than or equal to 5000 units per liter in the patient's initial test Consent of the patient's companions to perform the transplant and participate in the study

Exclusion criteria:

Having a pacemaker Heart failure Sepsis

Age

From **16 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Before starting the study, letter A is written on 15 sheets and letter B is written on 15 sheets, and each is placed in an envelope. Then, each eligible companion of patients who consented to participate in the study is asked to choose an envelope from among the envelopes. In this way, the patient will be randomly assigned to one of the two groups according to the envelope selected without the interference of the researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to comply with the conditions of double-blindness of the study, two doses of mannitol will be prepared by the nurse (without the knowledge of the researcher) daily and will be placed inside the bag and will be labeled A, B and will be given to the anesthetist (researcher) daily. Therefore, the researcher, the patient,

the person recording the clinical and basic information of the patients, as well as the statistical analyst, will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Medicine- Isfahan University of Medical Science (Ethics committee in research)

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.MUI.MED.REC.1398.240

Health conditions studied**1****Description of health condition studied**

Brain death

ICD-10 code

G93.82

ICD-10 code description

Brain death

Primary outcomes**1****Description**

Creatine phosphokinase

Timepoint

8 hours after receiving each dose of mannitol

Method of measurement

Blood test

2**Description**

Creatinine

Timepoint

8 hours after receiving each dose of mannitol

Method of measurement

Blood test

3

Description

Sodium

Timepoint

8 hours after receiving each dose of mannitol

Method of measurement

Blood test

4

Description

Potassium

Timepoint

8 hours after receiving each dose of mannitol

Method of measurement

Blood test

Secondary outcomes

1

Description

Blood pressure

Timepoint

2 hours after receiving each dose of mannitol

Method of measurement

Sphygmomanometer

2

Description

Heart beat

Timepoint

2 hours after receiving each dose of mannitol

Method of measurement

Pulse oximeter

Intervention groups

1

Description

First intervention group: In this group, 0.4 g/kg of mannitol along with 1 mEq of sodium bicarbonate per kilogram will be given in 20 minutes.

Category

Treatment - Drugs

2

Description

The second intervention group: In this group, 0.6 g/kg of mannitol along with 1 mEq of sodium bicarbonate per kilogram will be given in 20 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Parviz Kashefi

Street address

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8174675731

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kashefi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Parviz Kashefi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Parviz Kashefi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sayed Arash Mirsatari

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Non-faculty specialist doctor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available