Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 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
Isfehan
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

Soffe Blvd, Isfahan

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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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Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

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Person responsible for scientific inquiries

Contact

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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

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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