Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effect of Glucose-Insulin-Potassium to decrease level of Creatine Phosphokinase (CPK) in multiple trauma patients

Protocol summary

Study aim
Evaluation of the effect of GIK to decrease level of CPK in multiple trauma patients

Design
After obtaining the necessary permits, patients enter the study. The sample size is 70. Patients are divided into control and intervention groups in parallel and the control group treated with placebo and the intervention group treated with drug combination, CPK is measured and compared in both groups. The randomization method will be based on a simple randomization method using a random number table. The central randomization method will be used to hide allocation. Patients and clinician are not aware of the assigned group, so the study is a two-way blind.

Settings and conduct
Trauma patients admitted to Imam Hossein Hospital in Tehran with a CPK>3,000 and have the inclusion criteria are included in the study. The study was double-blind and the patient and clinicians involved were unaware of the content of fluid used (previously prepared by the non-involved person and hidden with a code). Based on the random number table, patients are divided into 2 groups control and intervention patients and receive placebo fluid or intervention drug. Patients in both groups receive an currently effective and approved treatment method, which is to double the fluid intake, and the intervention method, which is a solution of GIK, is added to the fluid intake.

Participants/Inclusion and exclusion criteria
Trauma patients over 18 years old and CPK>3000 and proper Sugar and Potassium and urine volume and not having mentioned underlying diseases

Intervention groups
The intervention group receives a combination of GIK, a 50 ml 50% Dextrose plus 10 units regular Insulin plus 10 mmol Potassium is prescribed in addition to treatment of the control group. The control group receives only the continuation of their treatment, i.e. twice the maintenance volume of normal saline.

Main outcome variables
Reduction of CPK using GIK

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211220053468N1**
Registration date: **2022-06-12, 1401/03/22**
Registration timing: **prospective**

Last update: **2022-06-12, 1401/03/22**
Update count: **0**

Registration date
2022-06-12, 1401/03/22

Registrant information

Name
Reza Beheshti monfared

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7343 3000

Email address
r_beheshti_m@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Glucose-Insulin-Potassium to decrease level of Creatine Phosphokinase (CPK) in multiple trauma patients

Public title

Effect of Glucose-Insulin-Potassium in Creatine Phosphokinase (CPK)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Trauma patient More than 18 years old Satisfaction with participation in the study CPK>3000 Urine output ≥ 0.5 cc/kg/hour

Exclusion criteria:

Absence of Angina, history of Malignant Hyperthermia, history of Myocarditis, Muscular Dystrophy, Rheumatoid Arthritis, Liver disease, Connective tissue disease, Heart failure Absence of Shock(BP more than 90 mmHg) Absence of Hypo- or Hyperglycemia(BS 100-250) Absence of Hypo- or Hyperkalemia(K 2.8 - 5)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method of the samples will be based on the simple randomization method and using a random number table, and the central randomization method will be used to hide the random allocation. The method is as follows: a non-involved person in the study reads the numbers from a table of random numbers (based on the total sample size of 70 people) from top to bottom, assigns even numbers to the drug solution of the control group and the odd numbers to the intervention group. As a result, the study drug combination or placebo is randomly selected based on the table. Each solution is then encrypted separately with a code. Clinical caregivers, who are different from the person preparing the drug combination, receive a coded solution (which can be a drug combination or placebo) when the patient is eligible for the study. Clinical caregivers do not know the order of the random number table and the number of samples, etc. Also, the person preparing the drug solution does not know the conditions of the patients and prepares the solution only based on the table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients enter the study after explaining how to do the study and obtaining consent. the drug combination of the control and intervention groups is prepared by the non-involved person in the study and the content of the solutions is hidden by entering the code, so patients, clinicians, researchers, evaluators and analysts are blind to the content of each solution. Patients are only aware of the possibility of accidentally receiving two types of treatment for their disease, and their conditions and side effects, and do not know to which study group they are assigned, so they are blind to their study group. After analyzing the information, the groups are divided according to the code allocated for study analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Shahid Arabi Ave, Yaman Ave, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.SBMU.MSP.REC.1401.108

Health conditions studied

1

Description of health condition studied

Trauma, Rhabdomyolysis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
level of blood creatine phosphokinase (CPK)
Timepoint
Creatine phosphokinase (CPK) blood levels are measured on the first day of the study (before the intervention) and on the first and second days after
Method of measurement
Creatine phosphokinase levels in blood samples are measured in a hospital laboratory

Secondary outcomes

1

Description
Blood creatinine level
Timepoint
Creatinine blood levels are measured on the first day of the study (before the intervention) and on the first and second days after
Method of measurement
Blood samples are measured in hospital laboratory

2

Description
Blood potassium
Timepoint
Blood potassium levels are measured on the first day of the study (before the intervention) and on the first and second days after
Method of measurement
Blood samples are measured in hospital laboratory

3

Description
Blood sugar
Timepoint
Blood sugar levels are measured on the first day of the study (before the intervention) and on the first and second days after
Method of measurement
Blood samples are measured in hospital laboratory

Intervention groups

1

Description
Intervention group: In this group, on the first and second day of the study, the pre-prepared solution, including a 50 ml vial of 50% Dextrose plus 10 units of regular Insulin plus 10 mmol of Potassium, is added to the patient's fluid intake as a single dose, which all patients receive as approved treatment.
Category
Treatment - Drugs

2

Description
Control group: In this group, No intervention is performed and only approved treatment is continued,that is, twice the amount of maintenance fluid (which according to the formula, the first 10 Kg of the patient's weight is equal to 100 ml/Kg and the second 10 Kg of the patient's weight is equal to 50 ml/Kg and the rest of the patient's weight is equal to 20 ml/Kg) Normal saline is administered as a 24-hour intravenous fluid.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Sara Salarian
Street address
Shahid Madani Ave
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
info@ehmc.ir
Web page address
https://www.ehmc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi (Vice- Chancellor in Research Affairs)
Street address
Arabi Ave., Yaman Ave.
City
Tehran
Province
Tehran
Postal code
1985717434
Phone
+98 21 2243 9951
Email
mpd@sbmu.ac.ir
Web page address
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Reza Beheshti Monfared
Position
Subspecialty Assistant
Latest degree
Specialist
Other areas of specialty/work
Critical care medicine
Street address
Madani Ave.
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
r_beheshti_m@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sara Salarian
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Critical care medicine
Street address
Shahid Madani Ave.
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
sarasalarian@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Reza Beheshti monfared
Position
Subspecialty resident
Latest degree
Specialist
Other areas of specialty/work
Critical care medicine
Street address
Imam Hussein Hospital, Shahid Madani St., Tehran
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 3000
Fax
Email
r_beheshti_m@yahoo.com

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Individual background data can be shared after unidentified individuals, the resulting data file can be published.
When the data will become available and for how long
Access is 6 months after the publication of the relevant article
To whom data/document is available
Researchers of scientific institutes
Under which criteria data/document could be used

For scientific research

From where data/document is obtainable

Communication with people responsible for scientific and public accountability

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

After receiving the request and confirming the identity, information can be provided according to the type of requested information.

Comments