

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@sbm.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