Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of "Glucose-Insulin-Potassium" administration on hemodynamic parameters and cardiac indices in patients admitted to the intensive care unit

Protocol summary

Study aim
Determining the effects of Glucose-Insulin-Potassium (GIk) administration on hemodynamic parameters and cardiac indexes in patients with shock admitted in Intensive care unit

Design
Clinical trial with before-after design (patients will compare to themselves after prescription). Admitted patients in intensive care unit will be enrolled with simple random sampling method " randomization table" base on admission number.

Settings and conduct
Patients admitted to the intensive care units of Sina Hospital and Imam Khomeini Hospital Complex affiliated to of Tehran University of Medical Sciences with hypotension and heart failure were randomly selected; glucose-insulin-potassium mixture was prescribed to them, and hemodynamic parameters by monitoring and cardiac indices with USCOM device were evaluated.

Participants/Inclusion and exclusion criteria
Entry condition: patients admitted in intensive care units in need of medical support due to systemic hypotension (shock) and decreased heart performance. Non-entry condition: 1. Patient non-cooperation 2. Age below 18 years 3. Diseases affecting the functioning of the cardiovascular system 4. Taking drugs that affect the performance of prescribed drugs

Intervention groups
"Insulin-glucose-potassium" mixture is prescribed to the patients admitted to the intensive care unit. The patient is evaluated in terms of hemodynamic parameters and cardiac indexes at regular intervals with USCOM device and monitoring of vital sign.

Main outcome variables
Blood pressure; heart rate; oxygen saturation;, stroke volume,; cardiac index; cardiac output; systemic vascular resistance

General information

Reason for update

Acronym
GIK

IRCT registration information
IRCT registration number: **IRCT20220730055585N1**
Registration date: **2022-08-10, 1401/05/19**
Registration timing: **prospective**

Last update: **2022-08-10, 1401/05/19**
Update count: **0**

Registration date
2022-08-10, 1401/05/19

Registrant information

Name
Ali Jabbari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3255 1935

Email address
dr.jabbari_a@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-11, 1401/05/20

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effects of "Glucose-Insulin-Potassium" administration on hemodynamic parameters and cardiac indices in patients admitted to the intensive care unit

Public title
Effects of "Glucose-Insulin-Potassium"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients admitted in intensive care units needing cardiovascular drug support due to systemic hypotension (shock) Decreased heart performance

Exclusion criteria:
Age below 18 years old Patients who do not participate or discontinue Pregnancy Brest feeding Central nerves system and cerebrovascular disease Anemia Chronic kidney disease Active bleeding Metastatic cancer IV drug user Chronic alcohol user Acute multi organ failure Brain death

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients admitted to the intensive care unit with different disease severity and etiology. Patient entry (patient selection) was based on simple random available sampling based on patient file number and randomization table.Patients were randomly selected to enter the study based on their case number.A table of random numbers was used for randomization.If the patient was excluded from the study, the next patient was replaced by chance.The entry of patients into the study continued until reaching the desired sample size (50 patients).

Blinding (investigator's opinion)
Double blinded

Blinding description
According to the design of the study (before-after), all patients will be the control group and the intervention group at some point in time (the changes in the parameters of patients after the administration of the drug will be compared with themselves).The patients do not know the time of the start of the study and the parameters are objective.The researcher (prescribing physician and operator of the USCOM device) is aware of the research process.The ward nurses (data collectors) and the data analyst are not aware of the study design and process.

Placebo
Not used

Assignment
Crossover

Other design features
study is designed base on "before- after" method. patients evaluated before GIK administration and during the therapy

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Sina Hospital

Street address
Anesthesia office, No. 3 building, Sina Hospital, Emam Khomeini street, Hasan abad square

City
Tehran

Province
Tehran

Postal code
1136746911

Approval date
2022-07-30, 1401/05/08

Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1401.051

Health conditions studied

1

Description of health condition studied
Hypotension, impaired hemodynamic parameters

ICD-10 code
I95

ICD-10 code description
Hypotension

2

Description of health condition studied
Impaired cardiac indexes (heart failure)

ICD-10 code
I50.20

ICD-10 code description
Unspecified systolic (congestive) heart failure

Primary outcomes

1

Description
Blood pressure

Timepoint
patient's entrance time to ICU, zero time (before prescription), 1h, 6h and 12h after prescription (during infusion)
Method of measurement
non invasive blood pressure - automated monitoring

2

Description
Stroke volume
Timepoint
patient's entrance time to ICU, zero time (before prescription), 1h, 6h and 12h after prescription (during infusion)
Method of measurement
Ultra sonic cardiac output monitoring (USCOM)

3

Description
Heart rate
Timepoint
patient's entrance time to ICU, zero time (before prescription), 1h, 6h and 12h after prescription (during infusion)
Method of measurement
Monitoring device

4

Description
Systemic Vascular Resistance
Timepoint
patient's entrance time to ICU, zero time (before prescription), 1h, 6h and 12h after prescription (during infusion)
Method of measurement
Ultra sonic cardiac output monitoring (USCOM)

Secondary outcomes

1

Description
Cardiac output
Timepoint
Patient's entrance time to ICU, zero time (before prescription), 1h, 6h and 12h after prescription (during infusion)
Method of measurement
Ultra sonic cardiac output monitoring (USCOM)

2

Description
Delivery Oxygen
Timepoint
Patient's entrance time to ICU, zero time (before prescription), 1h, 6h and 12h after prescription (during infusion)
Method of measurement
Ultra sonic cardiac output monitoring (USCOM)

Intervention groups

1

Description
Different patients are admitted in intensive care units with different severity and etiology. The selection of patients was done based on randomization. according to the design of the study, each patient was considered as a control group at some point of time and as an intervention group at some point. receiving Glucose-Insuline-potasium cocktail (GIK mixture); GIK cocktail infusion (insuline 15 IU+vial Kcl15% 20 mEq+Dextrose 50% 50ml) and in diabetic patients the same cocktail but Insuline 20 IU will apply. rate of infusion will be 10 ml/h for 12 hours. Cardiac index and hemodynamic parameters will evaluate in patient's entrance time to ICU, zero time (before prescription), 1 h, 6 h and 12 h after prescription (during infusion) by NIBP monitoring and USCOM device and parameters will compare before and after prescription in each one individually.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Ali Jabbari
Street address
Anesthesia office, Sina hospital, Emam khomeini street, Hasan Abad square
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Fax
+98 21 6634 8587
Email
hosp_sina@sina.tums.ac.ir
Web page address
https://sinahospital.tums.ac.ir/

2

Recruitment center
Name of recruitment center
Emam khomeini hospital
Full name of responsible person
Ali Jabbari
Street address
Anesthesia office, Emam khomeini hospital, keshavarz boulevard
City

Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1576
Email
bag@bmsu.ac.ir
Web page address
https://ikhc.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotuhi
Street address
Research consul, 6th floor, central organization of Tehran University of Medical Sciences, Ghods street, Keshavarz Blv
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
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
Ali Jabbari
Position
Assistant professor, fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesia office, No#4, Sina Hospital, Hasan Abad Sqr, Emam Khomeini street, Tehran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Fax
+98 21 6634 8587
Email
dr.jabbari_a@goums.ac.ir
Web page address
https://sinahospital.tums.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Jabbari
Position
Assistant professor, fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesia office, No#4, Sina Hospital, Hasan Abad Sqr, Emam Khomeini street, Tehran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Fax
+98 21 6634 8587
Email
dr.jabbari_a@goums.ac.ir
Web page address
https://sinahospital.tums.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Jabbari

Position
Assistant professor, fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesia office, No#4, Sina Hospital, Hasan Abad Sqr, Emam Khomeini street, Tehran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Fax
+98 21 6634 8587
Email
dr.jabbari_a@goums.ac.ir
Web page address
https://sinahospital.tums.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available