

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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	and the data analyst are not aware of the study design and process.
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	Placebo Not used
Public title Effects of "Glucose-Insulin-Potassium"	Assignment Crossover
Purpose Treatment	Other design features study is designed base on "before- after" method. patients evaluated before GIK administration and during the therapy
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	Secondary Ids empty
Age From 18 years old	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
Gender Both	Approval date 2022-07-30, 1401/05/08
Phase N/A	Ethics committee reference number IR.TUMS.SINAHOSPITAL.REC.1401.051
Groups that have been masked • Participant • Care provider • Data analyser	Health conditions studied 1 Description of health condition studied Hypotension, impaired hemodynamic parameters ICD-10 code I95 ICD-10 code description Hypotension
Sample size Target sample size: 50	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
Randomization (investigator's opinion) Randomized	Primary outcomes 1 Description Blood pressure
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)	

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

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 general inquiries

Contact

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

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