Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of two methods of intravenous potassium infusion on the correction of hypokalemia in Critically Ill Patients

Protocol summary

Study aim
Evaluation of the Serum Potassium Level in Different Modalities of Intravenous Potassium Infusion on Correction of Hypokalemia in Critically Ill Patients

Design
Single blinded randomized clinical trial

Settings and conduct
The patient, the person preparing the medication, and the person doing the blood sampling are not blinded, and only the researcher who places the patients in the study groups from the randomization table is blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 20 to 75 years ,Hospitalization in intensive care unit with blood potassium . Exclusion criteria: Heart disease, kidney disease, Diabetes, High blood pressure ,Gastrointestinal inflammatory disease ,Diarrhea and vomiting, Taking Inotrops.

Intervention groups
Intervention group one : Administration of 20 mEq of potassium chloride as infusion over one hour .
Intervention group two: Administration of 20 mEq of potassium chloride by infusion over three hours .

Main outcome variables
Serum potassium level, arrhythmia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N102**
Registration date: **2020-09-22, 1399/07/01**
Registration timing: **prospective**

Last update: **2020-09-22, 1399/07/01**
Update count: **0**

Registration date
2020-09-22, 1399/07/01

Registrant information

Name
Farzaneh Masihi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3647 4270

Email address
masihif@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of two methods of intravenous potassium infusion on the correction of hypokalemia in Critically Ill Patients

Public title
Evaluation of two methods of intravenous potassium infusion on the correction of hypokalemia in Critically Ill Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 20 to 75 years Hospitalization in intensive care unit with blood potassium level 3.5-2.5

Exclusion criteria:

Heart disease kidney disease Diabetes High blood pressure Gastrointestinal inflammatory disease Diarrhea and vomiting Taking diuretics Potassium supplementation ACEI Consumption Bicarbonate Cardiac arrhythmia Use of inotropic drugs Acid and base disorder

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into two groups of 32, using the table from www.randomization.org.Patients are divided into groups A and B at the arrival to the intensive care unit and treated according to their group

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient, the person preparing the medication, and the person doing the blood sampling are not blinded, and only the researcher who places the patients in the study groups from the randomization table is blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

IR.SUMS.MED.REC.1399.31

Health conditions studied

1

Description of health condition studied

Hypokalemia

ICD-10 code

E87.6

ICD-10 code description

Hypokalemia

Primary outcomes

1

Description

Correction of blood potassium levels in patients with hypokalemia with 3-hour potassium infusion

Timepoint

A blood sample is taken from the patient to check the blood level of potassium1 hour, 3 hours and 6 hours after the end of the infusion,

Method of measurement

A blood sample

Secondary outcomes

1

Description

Arrhythmia

Timepoint

1 hour, 3 hours and 6 hours after the end of the infusion,

Method of measurement

Monitoring

Intervention groups

1

Description

Intervention group:Administration of 20 mEq of potassium chloride as infusion over one hour

Category

Treatment - Drugs

2

Description

Intervention group:Administration of 20 mEq of potassium chloride by infusion over three hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Neda Zeinali

Street address
Namazi Hospital, Zand Street

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3235 1087

Email
nedaznl68@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Younes Ghasemi

Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3647 4270

Email
sacrc@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Neda Zeinali

Position
Anesthesiology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Anesthesiology Department, Faghihi Hospital, Zand Street

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3647 4270

Email
nedaznl68@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mansoor Masjedi

Position
Intensivist

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Anesthesiology Department, Faghihi Hospital, Zand Street

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3647 4270

Email
mansoormasjedi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Masihi

Position
BS in anesthesia/English Consultant
Latest degree
Master
Other areas of specialty/work
Anesthesiology
Street address
5th floor, Mohammad Rasoul Allah Research Tower, Khalili Street
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3647 4270
Email
masihifarzaneh@yahoo.com

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
Its against our policies.
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