

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Inotropes.

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 potassium 1 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