

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Intravenous Phosphorus in Comparison to Oral Phosphate for Treatment of hypophosphatemia in Critically ill Patients

Protocol summary

Study aim

Effect of Intravenous Phosphorus in Comparison to Oral Phosphate for Treatment of hypophosphatemia in Critically ill Patients

Design

Clinical trial with 2 groups: First group with oral therapeutic phosphate and second group with intravenous therapeutic phosphorus, Community based and pragmati, with a parallel group design of 140 patients, Randomised

Settings and conduct

This clinical trial study is carried out at the Masih Daneshvari Hospital. Among all patients over the age of 18 admitted to the ICU, we selected patients with hypophosphatemia according to the number of selected samples and randomly divided into two groups. One group is treated with oral phosphate and the other is treated with intravenous phosphorus.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient over 18 years old ;Admitted to Intensive Care Unit Exclusion criteria: The patient needs renal replacement therapy The patient that has a serum potassium concentration greater than 5 m.mol / L. Patient without basic phosphate level Chronic kidney failure with and without dialysis

Intervention groups

Patient with hypophosphatemia treatment with oral phosphate and intravenous phosphorus

Main outcome variables

Oral phosphate and intravenous phosphorus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020592N18**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **retrospective**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intravenous Phosphorus in Comparison to Oral Phosphate for Treatment of hypophosphatemia in Critically ill Patients

Public title

Comparison intravenous Phosphorus to Oral Phosphate for Treatment of hypophosphatemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient over 18 years old Admitted to Intensive Care Unit

Exclusion criteria:

The patient needs renal replacement therapy The patient that has a serum potassium concentration greater than 5 m.mol / L. Patient without basic phosphate level Chronic kidney failure with and without dialysis

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The groups randomization will performed based on the A and B allocation group. This process will managed by computerizing allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Masih Daneshvari Hospital the Edjucational ,
Research and Treatment center

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2016-06-20, 1395/03/31

Ethics committee reference number

IR.SBMU.MSP.REC.1396.111

Health conditions studied**1****Description of health condition studied**

Disorders of phosphorus metabolism and phosphatases

ICD-10 code

E83.3

ICD-10 code description

Disorders of phosphorus metabolism and phosphatases

Primary outcomes**1****Description**

Phosphor level

Timepoint

Before & After intervention

Method of measurement

Before intervention and 3 days after intervention

Secondary outcomes**1****Description**

Compensation of hypophosphatemia

Timepoint

Before & After intervention

Method of measurement

Before intervention and 3 days after intervention

2**Description**

Duration of stay in ICU

Timepoint

From the time of admission to the exit from the ICU

Method of measurement

Number of hospital days in ICU

Intervention groups**1****Description**

Intervention group: Patients with hypophosphatemia receiving oral phosphate.

Category

Treatment - Drugs

2**Description**

Intervention group: Patients with hypophosphatemia receiving intravenous phosphorus

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital the Edjucational ,
Research and Treatment center

Full name of responsible person

Dr Seyyed Mohamadreza Hashemian

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Masih Daneshvari Hospital

Full name of responsible person

Dr. Seyyed Mohammadreza Hashemian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Masih Daneshvari Hospital

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**

The Edjucational , Research and Treatment center

Full name of responsible person

Dr Seyyed Mohammadreza Hashemian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

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Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Somayeh Akhavan

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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