

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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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**Email**

iran.criticalcare@yahoo.com

### 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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Masih Daneshvari Hospital, Darabad Avenue, Shahid  
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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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The Edjucational , Research and Treatment center

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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### Person responsible for updating data

**Contact****Name of organization / entity**

The Edjucational , Research and Treatment center

**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