

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Evaluation of effectiveness and safety of Magnesium Carbonate and comparison with calcium carbonate in hyperphosphatemic end stage renal disease patients on chronic hemodialysis.

#### Protocol summary

##### Summary

Hyperphosphatemia is a common problem in end stage renal disease patients, and this patients need to use phosphorus binders. Calcium based phosphorus binders leads to calcium overload. Renagel and Lanthanum are expensive. Therefore a magnesium based phosphorus binder seems to be useful to be evaluated in these patients. The aim of this study was to evaluate the efficacy and safety of MgCo<sub>3</sub> tablets in hyperphosphatemic end stage renal disease and compare its effects with CaCo<sub>3</sub> tablets. Sample size was estimated 50 patients and selected from patients in Noor hospital dialysis center after getting a consent, with the inclusion criteria: 3 months on hemodialysis, P>5.5 mg/dl and age more than 18 years old. In case of irregular drug consumption or irregular hemodialysis, pregnancy, kidney transplantation, death, Ca × P > 54 in control group or Mg> 4 mg/dl the patient will be excluded. MgCo<sub>3</sub> tablets made in Amin pharmaceutical company. Patients were randomly divided in two groups to use either MgCo<sub>3</sub> tablets 250 mg trice daily or CaCo<sub>3</sub> 500 mg trice daily with meal for six weeks. The patients will be examined in each dialysis session to find the possible complications. With the respect to laboratory findings in two weeks intervals the drug doses will be adjusted. Ca, P, Alb, Mg, VBG, CRP will be checked before trial and each two weeks until the end of the study. Triglyceride, Cholesterol, LDL, HDL, iPTH will be checked before trial and at the end of the 6th week. At the end the efficacy and safety of MgCo<sub>3</sub> in hyperphosphatemia of these patients and serum Calcium, phosphorus, magnesium, iPTH, CRP, and lipid profile of two groups will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105186515N1**

Registration date: **2011-07-02, 1390/04/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-07-02, 1390/04/11

##### Registrant information

###### Name

Sepehr Raeisi Dehkordi

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1673 4114

###### Email address

sepehr\_raeisi@resident.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2010-01-21, 1388/11/01

##### Expected recruitment end date

2011-03-20, 1389/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of effectiveness and safety of Magnesium Carbonate and comparison with calcium carbonate in hyperphosphatemic end stage renal disease patients on chronic hemodialysis.

## Public title

Effects of Magnesium Carbonate tablet on hyperphosphatemia in patients under hemodialysis

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: age>18 years; serum phosphorus >5.5 mg/dl; at least 3 months on hemodialysis. exclusion criteria: serum magnesium > 4 mg/dl; pregnancy; previous parathyroidectomy; severe hyperparathyroidism(iPTH> 500 pg/ml); Medical disease cause diarrhea; Kidney transplant; Patient Death; Non-compliance of drug usage (at least 80% of prescribed drug must be used); Drug complications making the patient unable to continue the treatment; Lost hemodialysis more than one per month or Irregular hemodialysis

## Age

From **18 years** old to **90 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Ethical committee of Isfahan University of Medical Sciences

##### Street address

Davazeh-Shiraz, Hezar-Jerib St, Isfahan University of Medical Sciences

##### City

Isfahan

## Postal code

## Approval date

2011-01-04, 1389/10/14

## Ethics committee reference number

289205

## Health conditions studied

### 1

#### Description of health condition studied

End stage renal disease

#### ICD-10 code

N18.6

#### ICD-10 code description

End Stage Renal Disease

### 2

#### Description of health condition studied

hyperphosphatemia

#### ICD-10 code

E83.39

#### ICD-10 code description

classified in other phosphorus metabolism defect.

## Primary outcomes

### 1

#### Description

Changes in serum phosphorus level

#### Timepoint

Before trial and every 2 weeks till at the end of 6th week

#### Method of measurement

Lab data mg/dl

### 2

#### Description

Changes in Ca X P product

#### Timepoint

Before trial then every 2 weeks till the end of 6th week.

#### Method of measurement

Lab data mg/dl

### 3

#### Description

Changes in serum calcium

#### Timepoint

Before trial and every two weeks till the end of 6th week.

#### Method of measurement

Lab data mg/dl

### 4

#### Description

Changes in serum magnesium

#### Timepoint

Before trial and every two weeks till the end of 6th week.

**Method of measurement**

Lab data, mg/dl

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

Abdominal pain and diarrhea

**Timepoint**

Before trial then every 2 weeks till the end of 6th week.

**Method of measurement**

Clinical data(history and examination)

**2****Description**

Cardiac arrhythmia

**Timepoint**

Before trial then every 2 weeks till the end of 6th week.

**Method of measurement**

Clinical data(history and examination) and electrocardiography

**3****Description**

serum LDL, HDL, Tg, Chol,

**Timepoint**

Before trial then at the end of 6th week.

**Method of measurement**

Lab data mg/dl

**4****Description**

PTH

**Timepoint**

Before trial then at the end of 6th week.

**Method of measurement**

Lab data pg/ml

**5****Description**

CRP

**Timepoint**

before trial then every 2 weeks till the end of 6th week.

**Method of measurement**

lab data mg/l

**6****Description**

Serum HCo3

**Timepoint**

Before trial then every 2 weeks till the end of 6th week.

**Method of measurement**

Lab data mmol/l

**7****Description**

Blood pressure

**Timepoint**

Before trial then every 2 weeks till the end of 6th week.

**Method of measurement**

Clinical data(examination) mmHg

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

Control group: 25 ESRD patients on hemodialysis with serum phosphorus > 5.5 mg/dl will use CaCo3 500 mg trice daily with meal if  $6.5 > P > 5.5$  one Tablet if  $7.5 > P > 6.5$  two tablet will be added and if  $P > 7.5$  or If sever complication happened or if  $ca \times p > 54$  the patients will exclude from the study.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: 25 ESRD patients on hemodialysis with serum phosphorus > 5.5 mg/dl will use MgCo3 250 mg trice daily with meal if  $6.5 > P > 5.5$  one Tablet if  $7.5 > P > 6.5$  two tablet and if  $P > 7.5$  three tablets will be added. If sever complication happened (sever diarrhea or cardiac arrhythmia) or if  $Mg > 4$  mg/dl the patient will be excluded and get the needed treatment.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Noor and Ali-e-Asghar hospital

**Full name of responsible person**

Dr. S. Shahidi. Nephrologist

**Street address**

Noor and Ali-e-Asghar hospital, Hasht Behesht St.

**City**

Isfahan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Taleb Azarm

**Street address**

Vice chancellor for research, Isfahan University of Medical Sciences

**City**

Isfahan

**Grant name**

تحقیقاتی

**Grant code / Reference number**

289205

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

Yes

**Title of funding source**

Vice chancellor for research, Isfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Shahrzad Shahidi

**Position**

associated professor

**Other areas of specialty/work****Street address**

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**Position**

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**Full name of responsible person**

Dr. Sepehr Raeisi Dehkordi

**Position**

Internist. 2nd year resident of nephrology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty