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 MgCo3 tablets in hyperphosphatemic end stage renal disease and compare its effects with CaCo3 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. MgC03 tablets made in Amin pharmaceutical company. Patients were randomly divided in two groups to use either MgCo3 tablets 250 mg trice daily or CaCo3 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 MgCo3 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; sever 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 commitee 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 phosphoru metabolism defect.

Primary outcomes

1

Description
Changes in serum phosphorus level
Timepoint
Before trial and every 2 weeks till at the end of 6the 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 arhrythmia
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 x 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 proffesor
Other areas of specialty/work
Street address
Faculty of Medicine, Isfahan University of Medical Sciences, Darvazeh Shiraz
City
Isfahan
Postal code
Phone
+98 31 1668 5149
Fax
+98 31 1668 7898
Email
research@mui.ac.ir
Web page address
www.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Shahrzad Shahidi
Position
Nephrologist, associated proffesor
Other areas of specialty/work
Street address
Faculty of Medicine, Isfahan University of Medical Sciences, Darvazeh Shiraz
City
Isfahan
Postal code
Phone
+98 31 1668 5149
Fax
+98 31 1668 7898
Email
research@mui.ac.ir
Web page address
www.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Sepehr Raeisi Dehkordi
Position
Internist. 2nd year resident of nephrology
Other areas of specialty/work
Street address
Faculty of Medicine, Isfahan University of Medical Sciences, Darvazeh Shiraz
City
Isfahan
Postal code
Phone
+98 31 1668 5149
Fax
+98 31 1668 7898
Email
research@mui.ac.ir
Web page address
www.mui.ac.ir

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