Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

A comparative study of the effect of proton pump inhibitor and ranitidine on serum magnesium level and blood pressure in chronic hemodialysis patients with hypotention

Protocol summary

Study aim

Detecting the effect of Proton pump inhibitors and Ranitidine on serum magnesium and blood pressure in chronic Hemodialysis patients with hypotension

Design

In this clinical trial, all hemodialysis patients in hemodialysis ward of Bou Ali hospital in Ardabil from October 1 st since at least 6 months ago (three times a week each session lenght three to four hours and developed hypotension during dialysis. (SBP <90) will be included in the study until completion.

Settings and conduct

Before starting the study, all packets containing medication and placebo were coded as A and B, respectively, to conduct a double blind study. Patients will be selected by census and will be randomly treated using sealed envelopes containing code A and code B. Patient or doctor and neurse delivering drug packages will not be aware of the type of medicine contained in the envelope. Initially, blood samples were taken from all patients and blood magnesium and blood pressure levels were recorded and then three months after completion of the study magnesium levels were checked and recorded. Then the intervention group received placebo Ranitidine (150 mg) and Pentoprazole (40 mg) and control group Placebo Pentoprazole (40 mg) and Ranitidine (150 mg) daily for three months. At the end of the study, sampling will be performed again to measure the level of repeated magnesium and the blood pressure .

Participants/Inclusion and exclusion criteria

ESRD patients with hypotension during dialysis

Intervention groups

group A Administered Tab Pantaprazol 40 mg and Placebo of Ranitidine 150 mg and for B group Tab Ranitidine 150 mg and Placebo of Pantaprazol 40 mg administered.

Main outcome variables

فشار خون -سطح سرمی منیزیم

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150808023559N19**
Registration date: **2019-11-05, 1398/08/14**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-05, 1398/08/14**
Update count: **0**

Registration date

2019-11-05, 1398/08/14

Registrant information

Name
Somaieh Matin

Name of organization / entity
Ardabil University of Medicine Sciences

Country
Iran (Islamic Republic of)

Phone
+98 45 3373 3011

Email address
s.matin@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of proton pump inhibitor and ranitidine on serum magnesium level and blood pressure in chronic hemodialysis patients with hypotention

Public title
A comparative study of the effect of proton pump inhibitor and ranitidine on serum magnesium level and blood pressure in chronic hemodialysis patients with hypotention
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
ESRD patients with hypotension during dialysis
Exclusion criteria:
Serum Magnesium below 2 Antihypertensive therapy cancer Severe Congestive Heart Failure
Age
To **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Dialysis patients suffering from hypotension during dialysis will be selected by census and will be randomly treated using packages containing code A and B (including placebo).
Blinding (investigator's opinion)
Double blinded
Blinding description
Packages containing the drug and placebo are given to patients in code A and B, and neither the physician nor the nurse delivering the drug will know the contents of the package.
Placebo
Used
Assignment
Parallel
Other design features
Sample size is about 50 people ,Case :25 control :25

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences
Street address
Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱
Approval date
2019-08-18, 1398/05/27
Ethics committee reference number
IR.ARUMS.REC.1398.295

Health conditions studied

1

Description of health condition studied
Renal failure
ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
Hypotension
Timepoint
Before starting the Hemodialysis and every 60 minutes during Hemodialysis
Method of measurement
Mercury barometer

Secondary outcomes

1

Description
Hypomagnesiumia
Timepoint
Before and after intervention
Method of measurement
Lab

Intervention groups

1

Description

Intervention group: To first this group Tab Pantaprazol with a dose of 40 mg and Placebo of Ranitidine with a dose of 150 mg administered

Category

Treatment - Drugs

2

Description

Control group: To control group Tab Ranitidine with a dose of 150 mg and Placebo of Pantaprazol with a dose of 40 mg administered

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Hospital

Full name of responsible person

Elham Saeedi

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Varzesh Square

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5613643197

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Dr.Susan Mohammadikebar

Street address

Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

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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

Vice chancellor for research, Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Elham Saeedi

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr.Susan Mohammadikebar

Position

Assistant professor of Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Full name of responsible person
Elham Saeedi
Position
Internal medicine resident
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Medical doctor
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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