Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Long-Term Use of PPIs on Serum Electrolytes and Vitamins in Patients Reporting to Family Medicine Clinics in Pakistan

Protocol summary

Study aim

The aim of this study was to evaluate the long-term effects of proton pump inhibitors (PPIs) on electrolyte, mineral, and vitamin levels in patients requiring prolonged acid suppression therapy.

Design

A quasi-experimental, parallel-group trial conducted at a single center with a target sample of 60 participants. Participants were randomly assigned in a 1:1 ratio using computerized balloting. Outcome assessment was not blinded, and follow-up was conducted over 12 months.

Settings and conduct

The trial was conducted at the Department of Family Medicine, Pak Emirates Military Hospital (PEMH). It was a single-center study where participants were recruited from family medicine clinics. The trial was not blinded, and both participants and investigators were aware of the assigned treatments. The trial was carried out from January 2023 to March 2024, with participants followed for 12 months. Data was collected through clinical assessments, blood and stool samples, and interviews at baseline, 3, 6, and 12 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults (≥18 years) requiring long-term PPI therapy for GERD, chronic gastritis, or Zollinger-Ellison syndrome. Exclusion criteria: Patients with H. pylori-related peptic ulcers, malabsorption conditions, or pre-existing electrolyte/vitamin deficiencies needing treatment.

Intervention groups

Participants in the intervention group received oral omeprazole (20–40 mg daily), while the control group received famotidine or sucralfate. Electrolyte, mineral, and vitamin levels were monitored at baseline and at 3, 6, and 12 months. Nutritional supplements were not allowed, and those lost to follow-up were excluded from analysis.

Main outcome variables

The main outcome measures were changes in electrolyte, mineral, and vitamin levels, as well as treatment side effects and effectiveness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240505061656N1**
Registration date: **2025-01-22, 1403/11/03**
Registration timing: **retrospective**

Last update: **2025-01-22, 1403/11/03**
Update count: **0**

Registration date

2025-01-22, 1403/11/03

Registrant information

Name

Mehmood Hussain

Name of organization / entity

National University of Medical Sciences

Country

Pakistan

Phone

+92 346 0551070

Email address

mehmoodamcolian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-03-28, 1402/01/08

Actual recruitment start date

2023-01-20, 1401/10/30

Actual recruitment end date

2023-03-31, 1402/01/11

Trial completion date

2024-03-31, 1403/01/12

Scientific title

Effect of Long-Term Use of PPIs on Serum Electrolytes and Vitamins in Patients Reporting to Family Medicine Clinics in Pakistan

Public title

PPIs and micronutrients

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Adults ≥18 years of age Had an indication for long-term PPI therapy such as GERD, chronic gastritis or Zollinger Ellison syndrome and willing to participate in this study

Exclusion criteria:

Peptic ulcer disease secondary to H. pylori Medical condition that cause malabsorption (coeliac disease, chronic pancreatitis, gut resection, inflammatory bowel disease, chronic diarrhea etc) Individuals with pre-existing deficiencies or electrolytes / vitamins requiring intervention

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process for this trial was conducted using a simple randomization technique, where eligible participants were assigned to either the PPI group or the control group in a 1:1 ratio. Individual participants served as the unit of randomization, and no stratified randomization was applied. The randomization sequence was generated using a random number generator, ensuring an unbiased allocation of participants. Allocation concealment was not explicitly implemented, as the assignments were revealed to investigators at the time of patient enrollment.

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, Pak Emirates Military Hospital

Street address

Pak Emirates Military Hospital, Peshawer Road, Rawalpindi Cantt

City

Rawalpindi

Postal code

46000

Approval date

2023-03-01, 1401/12/10

Ethics committee reference number

A/28/EC/496/2023

Health conditions studied

1

Description of health condition studied

Adverse effects of PPIs

ICD-10 code

E83.42

ICD-10 code description

Hypomagnesemia

Primary outcomes

1

Description

Magnesium Levels

Timepoint

Baseline, 3-, 6-, 9- and 12-months

Method of measurement

Blood Sample

Secondary outcomes

1

Description

Calcium Levels

Timepoint

Baseline, 3-, 6-, 9-, 12-months

Method of measurement

Blood test

2

Description

Phosphate levels

Timepoint

Baseline, 3-, 6-, 9-, 12-months

Method of measurement

Blood test

3

Description
Serum iron
Timepoint
Baseline, 3-, 6-, 9-, 12-months
Method of measurement
Blood Test

4

Description
Vitamin B12 levels
Timepoint
Baseline, 3-, 6-, 9-, 12-months
Method of measurement
Blood test

5

Description
Folate levels
Timepoint
Baseline, 3-, 6-, 9-, 12-months
Method of measurement
Blood test

6

Description
Vitamin D levels
Timepoint
Baseline, 3-, 6-, 9-, 12-months
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group 1: Participants in this group received oral omeprazole 20-40 mg daily for long-term acid suppression therapy.
Category
Treatment - Drugs

2

Description
Control group: Participants in this group received either famotidine or sucralfate as an alternative treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pak Emirates ilitary Hospital
Full name of responsible person
Adil Khan
Street address
Pak Emirates Military Hospital, Peshawer Road, Rawalpindi Cantt
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Rawalpindi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Maryam Rehman
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46000
Phone
+92 323 5524774
Email
maryam-rehman@live.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Pak Emirate Military 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
Pak Emirates Military Hospital
Full name of responsible person
Mehmood Hussain
Position
Consultant
Latest degree
Specialist

Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data will be shared with journal in which study will be published.
When the data will become available and for how long
Data will remain available for scientific community.
To whom data/document is available
Only for academic / scientific community.
Under which criteria data/document could be used
Data will be available if asked for statistical analysis for meta-analysis or systemic reviews. Interested individuals can contact any of the authors for deidentified IPD.
From where data/document is obtainable
Data would be available from institute or from the authors of this research.
What processes are involved for a request to access data/document
Interested party can mail directly to first author using the email provided to obtain the data.
Comments