

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Military Hospital

Full name of responsible person

Adil Khan

Street address

Pak Emirates Military Hospital, Peshawer Road,
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Email

akkahn555@gmail.com

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 scientific inquiries**Contact****Name of organization / entity**

Pak Emirates Military Hospital

Full name of responsible person

Mehmood Hussain

Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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