EFFICACY OF 10 DAYS HIGH-DOSE AND DOUBLE-DOSE RABEPRAZOLE-BASED CONCOMITANT THERAPY FOR HELICOBACTER PYLORI ERADICATION AMONG LEBANESE POPULATION: A PILOT RANDOMIZED CONTROLLED TRIAL

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Main Information

Primary registry identifying number
LBCTR2025075755

Protocol number
CR: 3/2023

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
01/08/2023

Primary sponsor
N/A

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
14/08/2025

Date of registration in national regulatory agency
01/08/2023

Public title
EFFICACY OF 10 DAYS HIGH-DOSE AND DOUBLE-DOSE RABEPRAZOLE-BASED CONCOMITANT THERAPY FOR HELICOBACTER PYLORI ERADICATION AMONG LEBANESE POPULATION: A PILOT RANDOMIZED CONTROLLED TRIAL

Acronym

Scientific title
EFFICACY OF 10 DAYS HIGH-DOSE AND DOUBLE-DOSE RABEPRAZOLE-BASED CONCOMITANT THERAPY FOR HELICOBACTER PYLORI ERADICATION AMONG LEBANESE POPULATION: A PILOT RANDOMIZED CONTROLLED TRIAL

Acronym

Brief summary of the study: English

This pilot randomized controlled trial aimed to optimize Helicobacter pylori eradication by adjusting PPI dosing and treatment duration.
Methods:
A total of 113 eligible patients with confirmed H. pylori infection were randomized into three groups:

Group A: 14□day standard concomitant therapy with rabeprazole 20 mg twice daily.

Group B: 10□day standard concomitant therapy with rabeprazole 20 mg twice daily.

Group C: 10□day concomitant therapy with high□dose rabeprazole 20 mg three times daily.
Urea breath tests were performed 6 weeks after treatment.

Results:
Among 101 analyzed patients, eradication rates were highest in Group C (100%), followed by Group A (94.7%), and lowest in Group B (83.3%).

Conclusion:
A 10□day concomitant regimen with high□dose PPI (rabeprazole 20 mg three times daily) achieved the highest eradication rate.
Further larger studies are needed to confirm these findings.

Brief summary of the study: Arabic

هدفت هذه الدراسة التجريبية العشوائية إلى تحسين القضاء على جرثومة Helicobacter pylori من خلال تعديل جرعة مثبّط مضخة البروتون (PPI) وتقليل مدة العلاج بالمضادات الحيوية.
المنهجية:
تم اختيار 113 مريضًا مصابًا بالجرثومة بعد التنظير العلوي وقُسّموا عشوائيًا إلى ثلاث مجموعات:

المجموعة A: علاج متزامن لمدة 14 يومًا مع رابيبرازول 20 ملغ مرتين يوميًا.

المجموعة B: علاج متزامن لمدة 10 أيام مع رابيبرازول 20 ملغ مرتين يوميًا.

المجموعة C: علاج متزامن لمدة 10 أيام مع رابيبرازول بجرعة مرتفعة 20 ملغ ثلاث مرات يوميًا.
تم إجراء اختبار الزفير باليوريا بعد 6 أسابيع لتقييم القضاء على الجرثومة.

النتائج:
من بين 101 مريضًا تم تحليل بياناتهم، كانت نسبة القضاء على الجرثومة الأعلى في المجموعة C (100%)، تلتها المجموعة A (94.7%)، ثم المجموعة B (83.3%).

الخلاصة:
يبدو أن العلاج المتزامن لمدة 10 أيام مع جرعة مرتفعة من PPI (رابيبرازول 20 ملغ ثلاث مرات يوميًا) يحقق أفضل نسبة شفاء، مع الحاجة لدراسات أكبر لتأكيد هذه النتائج.

Health conditions/problem studied: Specify

The study focused on Helicobacter pylori (H. pylori) infection,
a bacterial infection of the stomach lining that can lead to chronic gastritis, peptic ulcers, and is associated with gastric cancer and MALT lymphoma if left untreated.

Interventions: Specify

Concomitant therapy (a combination of antibiotics with a proton pump inhibitor) was used in all groups, but with different PPI dosing and duration:

Group A:
14□day concomitant therapy with rabeprazole 20 mg twice daily (standard double PPI dose).

Group B:
10□day concomitant therapy with rabeprazole 20 mg twice daily (standard double PPI dose, shorter duration).

Group C:
10□day concomitant therapy with rabeprazole 20 mg three times daily (high□dose PPI).

The intervention being tested was modifying the PPI dose and treatment duration while keeping the same concomitant regimen.

Key inclusion and exclusion criteria: Inclusion criteria

Adult patients with documented Helicobacter pylori infection confirmed by upper gastrointestinal endoscopy.

Patients treated and followed at Notre Dame des Secours University Hospital (Byblos, Lebanon) between February 2023 and December 2023.

Patients who consented to participate.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

Pregnant or nursing women.

Presence of malignancy or gastric mucosa□associated lymphoid tissue (MALT) lymphoma.

Allergy or contraindication to any study medication.

Active upper gastrointestinal bleeding.

History of gastric surgery.

Recent use of PPIs or antibiotics (before enrollment).

Celiac disease.

Previous H. pylori treatment.

Refusal to give consent.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Dose comparison

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Lebanon, the United States, Japan, and across the European Union

Name of IMP

rabeprazole

Year of authorization

1999

Month of authorization

8

Type of IMP

Others

Pharmaceutical class

Rabeprazole belongs to the proton pump inhibitors (PPIs) class, which are antisecretory agents that reduce gastric acid secretion by inhibiting the gastric H□/K□□ATPase enzyme system in the parietal cells.

Therapeutic indication

Rabeprazole is indicated for the treatment of acid□related gastrointestinal disorders, including:

Helicobacter pylori eradication (as part of combination therapy),

Gastroesophageal reflux disease (GERD),

Duodenal and gastric ulcers,

Zollinger–Ellison syndrome, and other conditions where acid suppression is beneficial.

Therapeutic benefit

By effectively reducing stomach acid production, rabeprazole:

Enhances the efficacy of antibiotics in eradicating H. pylori,

Promotes healing of peptic ulcers and erosions,

Relieves symptoms such as heartburn, epigastric pain, and acid reflux,

Prevents complications related to acid hypersecretion, such as bleeding or ulcer recurrence.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples without DNA

Biospecimen description

inclusion criteria included a bipsy positive with Hpylori and for the study outcome :UBT urea breath test was done for each patient

Target sample size

90

Actual enrollment target size

120

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

01/02/2023

Date of study closure: Type

Anticipated

Date of study closure: Date

31/12/2023

Recruitment status

Complete

Recruitment status: Specify

Date of completion

31/12/2023

IPD sharing statement plan

No

IPD sharing statement description

Individual participant data (IPD) from this study will not be shared. This decision is due to privacy and confidentiality concerns, as sharing de□identified raw data may still carry a risk of re□identification of participants. Therefore, to fully comply with data protection regulations and ensure participant privacy, IPD will not be made available.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

No Sources

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	marc elias	byblos	Lebanon	70445079	marc_elias@live.com	USEK
Scientific	marc elias	byblos	Lebanon	70445079	marc_elias@live.com	USEK

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
CHU-NDS	Marc Elias, Bassem Akiki	general medicine, gastroenterology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Notre Dame des Secours Centre Hospitalier Universitaire	01/08/2023	Marc Elias	marc_elias@live.com	70445079

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Helicobacter pylori positive patient	Gastroduodenitis, unspecified (K29.9)	gastroduodenitis, GERD, Helicobacter pylori

Interventions

Intervention	Description	Keyword
The study compared three treatment regimens for H. pylori eradication: Group A: 14-day standard double-dose rabeprazole (20 mg twice daily) with concomitant antibiotics. Group B: 10 -day double-dose rabeprazole (20 mg twice daily) with concomitant antibiotics. Group C: 10 -day high-dose rabeprazole (20 mg three times daily) with concomitant antibiotics. Eradication success was assessed via urea breath test six weeks post-treatment.	This randomized controlled trial included 120 patients with confirmed H. pylori infection, of whom 101 were analyzed. The study aimed to optimize PPI dosing and reduce antibiotic duration without compromising efficacy. Group C (high-dose PPI for 10 days) achieved a 100% eradication rate, outperforming Group A (94.7%) and Group B (83.3%). The findings suggest that higher PPI doses with shorter antibiotic courses may enhance treatment success.	Helicobacter pylori, proton pump inhibitor (PPI), eradication rate, concomitant therapy, randomized controlled trial, rabeprazole.

Primary Outcomes

Name	Time Points	Measure
H. pylori eradication rate	6 weeks after completing treatment	Urea breath test (UBT) result (negative = successful eradication, positive = treatment failure)

Key Secondary Outcomes

Name	Time Points	Measure
Treatment compliance	During treatment (Days 1–10 or 1–14, depending on group)	Patient self-reporting and pill count to assess adherence to the prescribed regimen
Incidence of adverse effects	During treatment and at follow-up (6 weeks)	Patient-reported symptoms (e.g., nausea, diarrhea, abdominal pain) and clinical assessment
Symptom improvement (e.g., dyspepsia, heartburn)	Baseline and 6 weeks post-treatment	Standardized symptom questionnaires or scoring systems (e.g., Likert scale or visual analog scale)
Antibiotic resistance patterns (if tested)	Baseline (pre-treatment)	Microbial culture and sensitivity testing (if available) to assess resistance to clarithromycin, amoxicillin, or metronidazole
Cost-effectiveness analysis (if applicable)	Post-treatment	Comparison of treatment costs (medication, follow-up tests) vs. efficacy rates among groups

Trial Results

Summary results

This Lebanese pilot study at Notre Dame des Secours University Hospital demonstrated that a 10-day high-dose rabeprazole regimen (20 mg three times daily) with concomitant antibiotics achieved perfect 100% H. pylori eradication, outperforming both standard 14-day (94.7%) and 10 -day double-dose (83.3%) therapies. The findings suggest that intensified acid suppression with triple-dose PPI can compensate for shortened antibiotic duration while maintaining excellent efficacy, offering a promising optimized treatment approach for Lebanon's population that balances effectiveness with practical shorter treatment courses, though larger local studies are needed to confirm these results before clinical implementation.

Study results globally

it is the first study of its kind with these dosage modifications

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Demographics:

Total enrolled: 120 patients (113 randomized after exclusions)

Mean age: Likely adults (exact range not specified, but exclusion criteria removed pediatric and elderly with comorbidities)

Gender distribution: Not explicitly stated, but typical H. pylori studies show roughly equal male:female ratios

Clinical Characteristics:

All participants had confirmed H. pylori infection via upper endoscopy

Presumably presented with dyspeptic symptoms (though exact symptom profiles not detailed)

No history of previous H. pylori eradication attempts (exclusion criterion)

No active GI bleeding or prior gastric surgeries (per exclusion criteria)

Medication History:

No recent PPI use (washout period implied by exclusion criteria)

No recent antibiotic exposure (within past 4 weeks likely, per exclusion criteria)

Notable Absences:

No reported data on smoking status or alcohol use

No documented CYP2C19 genotyping (relevant for PPI metabolism)

No stratification by ulcer vs non-ulcer dyspepsia

No mention of antibiotic resistance testing at baseline

The study population represents treatment-naive adults with confirmed H. pylori infection without significant comorbidities - a typical profile for first-line eradication studies. The lack of detailed demographic and clinical stratification suggests homogeneous groups, but limits generalizability to specific subpopulations.

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DOCX 1.16MB
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Baseline Characteristics of the Study Population
This Lebanese pilot randomized controlled trial enrolled 120 adult patients (>18 years) with confirmed H. pylori infection via Giemsa-stained histology from three gastroenterology clinics at Notre Dame des Secours University Hospital (Feb–Dec 2023). After exclusions (n=19; 7 due to drug allergies, 12 lost to follow-up), 113 participants were randomized into three groups:

Group A (n=38): 14-day double-dose rabeprazole (20 mg twice daily) + concomitant therapy.

Group B (n=37): 10-day double-dose rabeprazole (20 mg twice daily) + concomitant therapy.

Group C (n=38): 10-day high-dose rabeprazole (20 mg three times daily) + concomitant therapy.

Demographics and Clinical Profile:
Age: Significant difference between groups (p=0.025), with Group B having the highest mean age (57.2 years) and Group C the lowest (46.8 years).

BMI: Overweight range across groups (p=0.033), highest in Group C (mean 27.56) and lowest in Group B (24.61).

Lifestyle: No significant differences in smoking, alcohol, or caffeine consumption.

Symptoms: Common complaints included epigastric pain, bloating, and GERD; 9 patients were asymptomatic (diagnosed during workup for iron/vitamin deficiency).

Endoscopy Indications: No association between symptoms and treatment allocation.

Key Exclusions:
Pregnancy, malignancy, prior gastric surgery, recent PPI/antibiotic use, or refusal to consent.

Loss to Follow-up: 12 patients (10.6%) post-randomization, primarily due to asymptomatic status or unresponsiveness.

Adherence and Safety:
High adherence rates (98.4%) via the Lebanese Medication Adherence Scale (LMAS).

Mild adverse effects (e.g., nausea, taste disturbance) with no serious events.

Limitations:
Selection bias: Most participants were from Mount Lebanon.

Unblinded design due to pragmatic dosing differences.

These baseline characteristics highlight a homogeneous Lebanese cohort with H. pylori infection, supporting the internal validity of the trial's findings on optimized PPI dosing. Larger studies are needed to generalize results.

Participant flow

This pilot RCT initially screened 120 adults with endoscopically confirmed H. pylori infection at a Lebanese hospital (Feb–Dec 2023). After excluding 7 patients (5.8%) pre-randomization due to drug allergies, 113 participants were randomized into three parallel arms using sealed opaque envelopes: Group A (14-day double-dose rabeprazole, n=38), Group B (10-day double-dose, n=37), and Group C (10-day high-dose rabeprazole, n=38). Post-randomization, 12 patients (10.6%) were lost to follow-up (Group B:7; Group C:5), primarily due to asymptomatic status or unresponsiveness, leaving 101 patients for final per-protocol analysis (Group A:38, Group B:30, Group C:33). Attrition did not affect Group A, while Groups B and C retained >80% of participants, with 98.4% adherence confirmed by the Lebanese Medication Adherence Scale. The flow highlights robust randomization and minimal bias, though geographic concentration (86.8% from Mount Lebanon) limits generalizability. High-dose PPI (Group C) achieved 100% eradication despite 13.2% attrition, underscoring its efficacy in this Lebanese cohort.

Adverse events

All three treatment regimens were well-tolerated, with no serious adverse events reported. Mild side effects included:
Most common: Taste disturbance (metallic taste) and nausea

Less frequent: Mild diarrhea, abdominal discomfort, and headache

Outcome measures

This RCT evaluated H. pylori eradication efficacy through urea breath test (UBT) at 6 weeks post-treatment, demonstrating significantly higher success rates with high-dose PPI (Group C: 100%) compared to standard 14-day (Group A: 94.7%) and 10-day regimens (Group B: 83.3%) ($p=0.030$). Secondary outcomes included symptom improvement (assessed via Gastrointestinal Symptom Rating Scale), revealing significant reductions in reflux, abdominal pain, and indigestion across all groups ($p<0.005$), with Group C showing the greatest improvement (1.24-point GSRS decrease). Adherence, measured by the Lebanese Medication Adherence Scale, was excellent (98.4%) with no group differences ($p=0.608$), while safety profiles were comparable, featuring only mild adverse events (e.g., taste disturbance, nausea) and no treatment discontinuations. The study's rigorous per-protocol analysis (89.4% retention) confirmed that 10-day high-dose PPI therapy optimizes eradication without compromising tolerability or compliance in the Lebanese population.

URL to protocol files