

# Comparison of Two Treatment Regimens for Helicobacter pylori Eradication in Lebanon

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## Main Information

### Primary registry identifying number

LBCTR2024095653

MOH registration number

NA

**Study registered at the country of origin**

Yes

### Type of registration

## Retrospective

**Date of registration in national regulatory agency**

### Primary sponsor

Holy Spirit University of Kaslik (USEK), School of Medicine and Medical Sciences.

Date of registration in primary registry

17/10/2024

Public title

## Comparison of Two Treatment Regimens for Helicobacter pylori Eradication in Lebanon

### Scientific title

# A Randomized Prospective and Crossover Study Comparing the Eradication Rate After 10 Days of Concomitant Therapy to Bismuth Quadruple Therapy Among a Sample of the Lebanese Population

### Brief summary of the study: English

This study aimed to compare the effectiveness of two treatment regimens, concomitant therapy and bismuth quadruple therapy, for the eradication of *Helicobacter pylori* among a sample of the Lebanese population. It was a randomized, prospective, and crossover study conducted between 2016 and 2018. Patients with active *H. pylori* infection were divided into two groups and treated with either regimen for 10 days. The eradication success was assessed using the 14C urea breath test. Both therapies were found to be equally effective as first-line treatments, but concomitant therapy showed higher efficacy when used as a second-line treatment.

### Brief summary of the study: Arabic

تهدف هذه الدراسة إلى مقارنة فعالية نظامي علاج، العلاج المتزامن والعلاج الرباعي المحتوي على اليزموت، في استئصال جرثومة المعدة. بين عامي 2016 و2018 عين من السكان اللبنانيين. كانت الدراسة عشوائية، استباقية، ومتقاطعة أجريت بين عامي \**Helicobacter pylori*\* وأيام. تم تقسيم نجاح الاستئصال 10 النقط إلى مجموعتين وتلقوا أحد النظامين العلاجيين لمدة \**H. pylori*\*. تقسيم المرضى المصابين بعدوى أظهرت النتائج أن كلا النظامين كانا فعالين بالتساوي كعلاج أولي، بينما أظهر العلاج المتزامن فعالية 14C باستخدام اختبار التنفس كعلاج ثانٍ. أعل، مع استخدام كلا النظامين.

**Health conditions/problem studied: Specify**

The health condition/problem studied in this trial is **\*\*Helicobacter pylori infection\*\***, which is associated with gastrointestinal disorders such as

Protocol number

H.pylori-2016-001

**Study registered at the country of origin: Specify**

**Type of registration: Justify**

The trial is being registered retrospectively to ensure transparency and contribute to scientific knowledge, as initial efforts focused on ethical approvals and study implementation.

**Primary sponsor: Country of origin**

Lebanon

**Date of registration in national regulatory agency**

### Acronym

CTBQT-H. pylori

### Acronym

RCT-COMP-BQT



gastritis, peptic ulcers, and an increased risk of gastric cancer and MALT lymphoma.

## Interventions: Specify

The interventions in the study were two treatment regimens for the eradication of *Helicobacter pylori*:

1. **Concomitant Therapy**: A 10-day regimen consisting of esomeprazole 40 mg twice daily, amoxicillin 1 g twice daily, clarithromycin 500 mg twice daily, and metronidazole 500 mg twice daily.
2. **Bismuth Quadruple Therapy**: A 10-day regimen consisting of esomeprazole 40 mg twice daily, along with a capsule containing bismuth, tetracycline, and metronidazole (3 capsules taken four times a day).

Patients who did not achieve eradication with the first treatment were switched to the other therapy.

## Key inclusion and exclusion criteria: Inclusion criteria

The inclusion criteria for the study were:

1. **Positive *Helicobacter pylori* infection** confirmed through histological findings.
2. **No prior eradication therapy** for *Helicobacter pylori*.
3. **Written informed consent** provided by all participants.

These criteria ensured that the study focused on patients with active *H. pylori* infections who had not undergone previous treatment.

## 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

75

## Key inclusion and exclusion criteria: Exclusion criteria

The exclusion criteria for the study were as follows:

1. **Recent exposure to antibiotics**.
2. **History of allergy or intolerance** to any of the components in the treatment regimens.
3. **Presence of gastric cancer** confirmed by histological findings.
4. **Patients who had undergone prior eradication therapy** for *Helicobacter pylori*.

These criteria ensured the exclusion of patients who might have confounding factors affecting treatment outcomes or safety.

## Type of study

Observational

## Type of intervention

N/A

## Type of intervention: Specify type

N/A

## Trial scope

N/A

## Trial scope: Specify scope

N/A

## Study design: Allocation

N/A

## Study design: Masking

N/A

## Study design: Control

N/A

## Study phase

N/A

## Study design: Purpose

N/A

## Study design: Specify purpose

N/A

## Study design: Assignment

N/A

## Study design: Specify assignment

N/A

## IMP has market authorization

## IMP has market authorization: Specify

## Name of IMP

## Year of authorization

## Month of authorization

**Type of IMP**

**Pharmaceutical class**

**Therapeutic indication**

**Therapeutic benefit**

**Study model**

Case-Crossover

**Study model: Specify model**

N/A

**Study model: Explain model**

It included a crossover component, where patients who did not respond to the initial treatment were switched to the alternative therapy and re-evaluated.

**Time perspective**

Prospective

**Time perspective: Specify perspective**

N/A

**Time perspective: Explain time perspective**

It was prospective, meaning data were collected as the study progressed.

**Target follow-up duration**

6

**Number of groups/cohorts**

2

**Target follow-up duration: Unit**

weeks

**Biospecimen retention**

None retained

**Biospecimen description**

NA

**Target sample size**

427

**Actual enrollment target size**

374

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

01/03/2016

**Date of study closure: Type**

Actual

**Date of study closure: Date**

01/12/2018

**Recruitment status**

Complete

**Recruitment status: Specify**

**Date of completion**



31/12/2018

**IPD sharing statement plan**

No

**IPD sharing statement description**

NA

**Additional data URL**

NA

**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	Jad Chidiac	Paris	France	0763918897	jad_chidiac@live.com	USEK
Scientific	Charbel Yazbeck	Jbeil	Lebanon	03334998	charbelyazbeck@usek.edu.lb@live.com	USEK



## Centers/Hospitals Involved in the Study

No Centers/Hospitals

## Ethics Review

No Reviews

## Countries of Recruitment

Name
Lebanon

## Health Conditions or Problems Studied

No Problems Studied

## Interventions

No Interventions

## Primary Outcomes

No Outcomes

## Key Secondary Outcomes

No Outcomes



## Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files