



# Gastroesophageal Reflux Disease and Probiotics

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## Main Information

**Primary registry identifying number**

LBCTR2023105464

**Protocol number**

LBCTR2023105464

**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**

31/10/2023

**Primary sponsor**

Lebanese American University

**Primary sponsor: Country of origin**

Lebanon

**Date of registration in primary registry**

21/11/2023

**Date of registration in national regulatory agency**

31/10/2023

**Public title**

Gastroesophageal Reflux Disease and Probiotics

**Acronym**

**Scientific title**

Gastroesophageal Reflux Disease and Probiotics

**Acronym**

GERD and Probiotics

**Brief summary of the study: English**

In this study we aim at determining if GERD symptoms are alleviated by the administration of certain strains of Gram-positive organisms administered as probiotics. The expected duration of the study is 2 months. It is an experimental study whereby we are trying to determine if the administration of probiotics would alleviate reflux symptoms. The approximate number of participants to be included is 400.

**Brief summary of the study: Arabic**

تهدف في هذه الدراسة إلى تحديد ما إذا كانت أعراض الارتجاع المعدي المريئي يتم تخفيفها عن طريق إعطاء سلالات معينة من الكائنات إيجابية الجرام التي يتم تناولها كبروبيوتيك. المدة المتوقعة للدراسة شهرين. إنها دراسة تجريبية نحاول من خلالها تحديد ما إذا كان إعطاء البروبيوتيك 400 سيخفف من أعراض الارتجاع. العدد التقريبي للمشاركين الذين سيتم تضمينهم هو

**Health conditions/problem studied: Specify**

Gastroesophageal Reflux Disease

**Interventions: Specify**

Probiotics

**Key inclusion and exclusion criteria: Inclusion criteria**

- Patients with mild to moderate GERD symptoms (diagnosed on basis of clinical presentation)
- Patients with GERD regardless of prior treatment for GERD but not currently on PPIs over at least 4 weeks



**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**

50

**Key inclusion and exclusion criteria: Exclusion criteria**

- Patients less than 18 years or above the age of 50
- Prior bariatric surgery
- Epigastric mass
- Prior endoscopy showing severe erosive esophagitis LA-C or LA-D
- Alarm symptoms: weight loss, anemia, dysphagia or odynophagia, family history of malignancy, melena, hematemesis, nausea and vomiting
- Pregnant women
- Malignancy, IBD, immunosuppressive therapy
- Advanced cardiac disease
- Chronic uninterrupted use of PPI
- ESRD
- Use of probiotics within the last 6 months

**Type of study**

Interventional

**Type of intervention: Specify type****Type of intervention**

Pharmaceutical

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**

Placebo

**Study phase**

N/A

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Other

**Study design: Specify assignment**

Placebo-Controlled

**IMP has market authorization**

Yes, Lebanon

**IMP has market authorization: Specify****Name of IMP**

Probiolife

**Year of authorization****Month of authorization****Type of IMP**

Others

**Pharmaceutical class**

Probiotic

**Therapeutic indication**

Gastroesophageal reflux disease symptoms

**Therapeutic benefit**

Possible resolution or decrease of gastroesophageal reflux disease symptoms

**Study model****Study model: Explain model**



N/A

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**

None retained

**Biospecimen description**

N/A

**Target sample size**

400

**Actual enrollment target size**

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

15/11/2023

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

01/04/2024

**Recruitment status**

Pending

**Recruitment status: Specify**

**Date of completion**

**IPD sharing statement plan**

No

**IPD sharing statement description**

N/A

**Additional data URL**

**Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Lebanese American University Institutional Review Board	LAUMCRH.RC1.13/Oct/2023

## Sources of Monetary or Material Support

Name
Pharma M SAL

## Secondary Sponsors

No Sponsors

## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Omar El Masri	Beirut	Lebanon	71354271	omar.elmasri@lau.edu	Lebanese American University
Scientific	Rajaa Chatila	Beirut	Lebanon	03539849	rajaa.chatila@lau.edu.lb	Lebanese American University

## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Lebanese American University Medical Center - Rizk Hospital	Dr. Rajaa Chatila	Gastroenterology	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Lebanese American University- University Medical Center Rizk Hospital	13/10/2023	LAU IRB	irb@lau.edu.lb	01786464



## Countries of Recruitment

**Name**

Lebanon

## Health Conditions or Problems Studied

Condition	Code	Keyword
Gastroesophageal Reflux Disease	Gastro-oesophageal reflux disease (K21)	GERD

## Interventions

Intervention	Description	Keyword
Probiotic	Multi-strain probiotic, that contains Lactobacillus rhamnosus GG, Saccharomyces boulardii, Bifidobacterium breve, Bifidobacterium lactis, Lactobacillus acidophilus, Lactobacillus plantarum, Lactobacillus reuteri, prebiotics, and zinc (from citrate) (Probiolife®) .	Probiotic

## Primary Outcomes

Name	Time Points	Measure
Gastroesophageal Reflux Disease Symptoms	8 weeks	The Gastroesophageal Reflux Disease-Health Related Quality of Life instrument

## 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**