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

نهدف 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 سيخفف من أعراض الارتجاع. العدد التقريبي للمشاركين الذين سيتم تضمينهم هو 400.

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

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

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