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A food supplement based on probiotics, vitamin PP and vitamin B2 can improve heartburn symptoms/dyspeptic disorders and heartburn-related quality of life in subjects with mild to moderate gastroesophageal reflux disease (GERD)

Submission date 25/01/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 31/01/2024	**Overall study status** Completed	
Last Edited 30/01/2024	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Heartburn is common worldwide and its prevalence may be increasing. Symptoms are typically treated with medications such as antacids, proton pump inhibitors (PPI) and histamine-2 receptor antagonists. Although proton pump inhibitors are the standard of care for gastroesophageal reflux disease (GERD), these medications may not be effective for non-erosive disease. Neither proton pump inhibitors nor histamine-2 receptor antagonists may be effective for intermittent use. Further, antacids have been reported to cause side effects, including stomach pain, constipation, nausea and vomiting, and must be used with caution by some patient populations such as those with kidney failure.
Thus, for occasional mild or moderate heartburn symptoms, the effectiveness of new nonpharmacological approaches to heartburn relief such as dietary supplements requires exploration.
The study aims to evaluate the effectiveness of a food supplement (Pilorex®) on heartburn symptoms and dyspeptic disorders relief and heartburn-related quality of life in subjects with mild to moderate gastroesophageal reflux disease (GERD). Pilorex® is a food supplement of vitamins C, B1, B2, B6, PP, pantothenic acid, folic acid, and lactic acid bacteria, with fermented soy protein.

Who can participate?
People aged 18 to 50 years old with mild or moderate heartburn

What does the study involve?
Participants are randomly assigned to two groups to receive four tablets per day of the active product or a placebo (two in the morning upon waking up before breakfast, and two after dinner

/before going to bed) with a glass of water for 28 days. All participants are interviewed and will receive a food diary and a symptom questionnaire. Participants will return to the Medical Center at 14 days, bringing back the food diary and the symptoms questionnaire, receiving further forms to fill, and answering questionnaires.

What are the possible benefits and risks of participating?
Participants who take the active product could benefit from an improvement in gastroesophageal reflux disease symptoms. There are no notable risks involved with taking part in this study.
Risks associated with the intake of the product are considered from low to very low, in the absence of allergy/intolerances to product ingredients. Other ingredients in the formula of the product are commonly used in dietary supplements. All measurements carried out are not invasive (questionnaire).

Where is the study run from?
Nutratech Srl (Italy)

When is the study starting and how long is it expected to run for?
June 2023 to December 2023

Who is funding the study?
Bromatech Srl (Italy)

Who is the main contact
Dr Francesco Tursi, francesco.tursi@complifegroup.com

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
H.E.HU.HV.NMS00.050.03.00_ NT0000683/23

Study information

Scientific Title
Evaluation of the efficacy of a food supplement based on probiotics, vitamin PP and vitamin B2 in improving heartburn symptom/dyspeptic disorders and heartburn-related quality of life in subjects with mild to moderate gastroesophageal reflux disease (GERD): a randomized, double-blind, placebo-controlled clinical study

Acronym
PILOREX

Study objectives
The study aims to evaluate the efficacy of a food supplement on heartburn symptom/dyspeptic disorders relief and heartburn-related quality of life in subjects with mild to moderate gastroesophageal reflux disease (GERD).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/08/2023, Independent Ethical Committee for Non-Pharmacological Clinical Study Trials (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; a. scudieri@studinonfarmacologici.it), ref: 23/10

Study design
Single-centre double-blinded randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Mild to moderate Gastro-Esophageal Reflux Disease (GERD)

Interventions
Healthy male and female subjects aged from 18 to 50 years old (included) were enrolled and equally allocated to the placebo and food supplement group by using a computer-generated restricted randomized list.

Participants are randomly assigned to the Active Group and to the Placebo Group to receive four tablets per day of products (two in the morning upon waking up before breakfast, two after dinner/before going to bed) with a glass of water for 28 days.

The active product contains non-GMO soy proteins fermented by Lactobacillus bulgaricus (77%), Lactobacillus acidophilus LA14, Vitamin C, Niacin, Calcium pantothenate, Vitamin B2, Vitamin B6, Vitamin B1, Folic acid and Excipients. The placebo group received tablets containing only excipients.

Intervention Type
Supplement

Primary outcome measure
Heartburn episodes in adult subjects with mild to moderate GERD, measured using a questionnaire evaluating the severity and frequency of episodes on a daily basis for 28 days

Secondary outcome measures
Quality of life in subjects with mild to moderate GERD, measured using a questionnaire (GERD QOL) at T0-T14 and T28

Overall study start date
02/06/2023

Completion date
01/12/2023

Eligibility

Key inclusion criteria

1. Healthy male and female subjects aged 18 to 50 years old (inclusive), aware of the study procedures and having signed an informed consent form
2. Subjects who experienced mild or moderate heartburn according to Dyspepsia questionnaire (modified Leeds card)
3. Subjects used over-the-counter (OTC) products for heartburn, food supplements, or dietary manipulation to relieve heartburn symptoms during the previous 3 months
4. Willingness not to use products apart from the product tested throughout the study period and antiacids**
5. Willingness not to vary the normal daily routine (i.e. lifestyle, physical activity, usual diet, fluid intake etc)
6. Subjects under effective contraception (oral/not oral) therapy
7. Available and willing to follow the procedure of the study protocol
8. Subjects who have not been recently involved in any other similar study (at least 2 months of wash-out)
9. Subjects registered with the National Health Service (NHS)
10. Willingness to respect the instructions given by the investigator as well as to respect the study constraints and specific requirements
11. The pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) should be stable for at least 1 month without any changes expected or planned during the study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
56

Total final enrolment
56

Key exclusion criteria
1. Subjects not fulfilling the inclusion criteria above
2. Alimentary/eating disorders (i.e. bulimia, psychogenic eating disorders, etc)
3. Severe heartburn problem during the week prior to the study
4. Previous or current treatment for any gastrointestinal diseases or illnesses
5. Diagnosis of Barrett’s esophagus
6. Previous upper gastrointestinal surgery
7. Clinically significant GI bleeding within the last 3 months
8. Esophagitis not related to acid reflux

9. Known hypersensitivity or allergy to one of the active ingredients
10. Bleeding disorder, Zollinger–Ellison Syndrome, duodenal/gastric ulcer and upper gastrointestinal malignancy
11. Alcohol or drug abuse
12. Under pharmacological treatments (abuse of FANS, antibiotics, etc) known to interfere with the tested product
13. Clinical history with relevant presence of any disorder or administration of drugs/food supplement that can potentially interfere with the treatment under study
14. Pregnant or breastfeeding women
15. Known food intolerance or food allergy
16. Unstable medical diseases (cardiac arrhythmias or ischemia, uncontrolled hypertension and hypotension, diabetes mellitus, kidney failure)
17. History of paralysis or cerebral vascular accident
18. Subjects participating or planning to participate in other clinical trials
19. Adult protected by the law (under guardianship, or hospitalized in a public or private institution, for a reason other than the research, or incarcerated)

Date of first enrolment
04/09/2023

Date of final enrolment
07/10/2023

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Bromatech Srl

Results and Publications

Publication and dissemination plan
Planned publication in a high -impact peer-reviewed journal

Intention to publish date
30/03/2024

Individual participant data (IPD) sharing plan
Raw data will be stored in Nutratech Srl servers. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study Sponsor by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years in Nutratech servers. In the raw data tables, subjects are identified by a means of a code generated by the Nutratech Srl volunteer’s management software. The code is composed of a letter (N), a letter, 4 digits, and a letter. The access to the study raw data is allowed only to the study director and the person designated by him to elaborate the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and the inferential analysis (data normality and statistical test).

IPD sharing plan summary
Stored in non-publicly available repository