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The beneficial effect of ingestion of a food supplement based on a pool of digestive enzymes in people with functional dyspepsia

Submission date
14/06/2023

Recruitment status
No longer recruiting

Registration date
28/06/2023

Overall study status
Completed

Last Edited
29/11/2023

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Functional dyspepsia represents a problem for society, both in terms of health costs and the worsening of the quality of life of patients. Symptoms reported by patients with dyspepsia include bloating, early satiety, postprandial fullness, nausea, anorexia, heartburn, regurgitation, and frequent belching.
A deficiency or possible dysfunction of digestive enzymes may be an important factor in dyspepsia. Digestive enzymes aid digestion by breaking down carbohydrates, proteins, and lipids, promoting their absorption. It therefore may be useful to create products composed of these enzymes that are stable in the intestinal environment and are able to improve the pre-existing enzymatic activity. In fact, there are some clinical studies which demonstrate the positive effect of a variety of digestive enzymes, also used in combination or in addition to probiotics.
The aim of this study is to evaluate the effectiveness of supplementing the diet with a pool of digestive enzymes, at improving functional dyspepsia symptoms and quality of life.

Who can participate?
Patients aged 18-59 years who have functional dyspepsia

What does the study involve?
Participants are randomly allocated to consume a food supplement containing digestive enzymes or a placebo (dummy) for 60 days.

What are the possible benefits and risks of participating?
No risks are foreseen. Participants taking the food supplement may experience an improvement in dyspepsia symptoms and quality of life. However, there may be no benefit.

Where is the study run from?
Comegen, Naples (Italy)

When is the study starting and how long is it expected to run for?
October 2022 to September 2023

Who is funding the study?
Istituto Nazionale Biostrutture e Biosistemi (Italy)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DISPEPSIA22_01

Study information

Scientific Title
Evaluation of the efficacy of digestive enzyme supplementation in patients with functional dyspepsia for the improvement of quality of life: randomized, double-blind, placebo-controlled, monocentric, clinical study

Acronym
DISPEPSIA22

Study objectives
The aim of this study was to evaluate the effectiveness of supplementing the diet with a pool of digestive enzymes, in improving functional dyspepsia symptoms, and, consequently, the individual's quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/11/2022, Comitato Etico Campania Centro (Strada Comunale del Principe 13/a, Naples, 80145, Italy; +39 (0)812544515; COMITATOETICO@aslnapoli1centro.it), ref: 591

Study design
Interventional monocentric randomized parallel double-blind placebo-controlled clinical trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Functional dyspepsia

Interventions
The subjects recruited in the present clinical study will consume a food supplement based on a pool of digestive enzymes derived from fungal microorganisms (amylase, protease, and lactase from Aspergillus oryzae, cellulase from Trichoderma reesei, lipase form Rhizopus oeyzae) or a placebo for 60 days based on the randomization group.

The randomization sequence will be generated by a statistician using STATA 16 software (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) and the randomization list will be kept hidden. The participants will be assigned to each of the two treatment groups (food supplement or placebo) casually and by simple randomization (1:1 allocation ratio). The

randomization code will consist of a three-digit number as indicated in the respective Case Report Form (CRF).

In the clinical study, 120 participants will be enrolled and divided into two groups (60 for each group):

Group 1: food supplement containing the pool of digestive enzymes.
Group 2: placebo.

The supplementation consists of two capsules/day for a total dosage of 400 mg/die of the digestive enzyme pool.

Participants will undergo four visits (baseline = t0; after 30 days of treatment = t1; after 60 days of treatment = t2) in an outpatient setting. After each clinical visit, all data are filled in the CRF by physicians.

During the screening visit, subjects will undergo the following investigation to understand if they meet the study participation requirements:
Functional dyspepsia diagnosis confirmation, using Rome IV criteria, which predict, in an individual who does not present organic causes, the occurrence of at least one of the following symptoms, in the 6 months preceding the diagnosis:
1. Postprandial filling (at least 3 days in a week)
2. Early satiety (at least 3 days in a week)
3. Epigastric pain (at least 1 day in a week)
4. Heartburn (at least 1 day in a week)
Adherence to the Rome IV criteria for functional dyspepsia must have been met for at least 3 months.

Subsequently, all enrolled subjects will undergo the following:
At t0, t1 and t2 (at baseline, 30 and 60 days from the start of treatment) filling the Nepean Dyspepsia Index-Short Form (NDI-SF), Pittsburgh Sleep Quality Index (PSQI) questionnaires, and a Visual Analogue Scale (VAS) for general perceived pain evaluation, administered by the investigating physician.

Intervention Type
Supplement

Primary outcome(s)
Functional dyspepsia symptoms measured using the Nepean Dyspepsia Index-SF (NDI-SF) at baseline (t0), 30 days (t1), 60 days of treatment (t2)

Key secondary outcome(s))
1. Perceived general pain measured using the Visual Analog Scale (VAS) at baseline (t0), 30 days (t1), 60 days of treatment (t2)
2. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline (t0), 30 days (t1), 60 days of treatment (t2)

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Aged 18-59 years of both sexes
2. Diagnosis of functional dyspepsia according to the Rome IV criteria
3. Have not taken antibiotics or other drugs whose primary site of action is the gastrointestinal tract in the month prior to screening, except those used in the treatment of functional dyspepsia itself (drug intake has been recorded)
4. Have agreed not to significantly modify their normal eating habits during the study period
5. Not using other food supplements throughout the study period
6. Able to understand and sign the informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
59 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Aged <18 and >59 years
2. Have a medical history or condition that could affect the subject's safety or negatively impact the validity of the study results
3. Pregnant or breastfeeding women
4. Cognitive impairments which could hinder the response to questionnaires
5. History of allergy to ingredients contained in the study treatments (dietary supplement and placebo)
6. Using drugs that could interfere with gastrointestinal motility, except those used in the treatment of functional dyspepsia itself (drug intake has been recorded)
7. Other pathologies of the gastrointestinal system (gastroesophageal reflux, irritable bowel syndrome [IBS], small intestinal bacterial overgrowth [SIBO])
8. Malabsorption
9. History of addiction or abuse of medications or drugs
10. Continued to abuse alcohol over time (alcoholics), smokers or ex-smokers who have quit less than a year ago
11. Celiac disease
12. Eating disorders
13. Heart disease

14. Chronic hepatic, biliary and pancreatic pathologies, neoplastic pathologies, genetic-metabolic diseases or diabetes

Date of first enrolment
16/06/2023

Date of final enrolment
23/06/2023

Locations

Countries of recruitment
Italy

Study participating centre
Comegen
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Sponsor information

Organisation
Istituto Nazionale Biostrutture e Biosistemi

ROR
https://ror.org/043bhwh19

Funder(s)

Funder type
Research organisation

Funder Name
Istituto Nazionale Biostrutture e Biosistemi

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/11/2023	29/11/2023	Yes	No