

Probiotic and Ginger Supplement for Symptoms and Quality of Life in Functional Dyspepsia (SUBTILE)

NCT07212907

Status	RECRUITING
Phase	Not Applicable
Sponsor	Biocodex
Enrollment	198 participants

Key Eligibility Criteria

Inclusion (7)

- Adults (male or female) aged ≥18 years.
- Diagnosis of functional dyspepsia (FD) according to Rome IV criteria, with normal upper endoscopy including negative Helicobacter pylori test. Rome IV criteria define FD as the presence of one or more of the following symptoms: bothersome postprandial fullness, early satiety, epigastric pain, or epigastric burning, occurring at least 3 days per week during the last 3 months, with symptom onset at least 6 months prior to diagnosis.
- PAGA-SYM total score >1 at baseline.
- Ability to comply with study requirements and provide signed written informed consent before any study-related procedures.
- Ability to complete the patient diary and questionnaires, in the investigator's opinion (sufficient reading and language comprehension).

... and 2 more (see full listing online)

Exclusion (16)

- Use within 2 weeks prior to baseline of treatments that could interfere with study evaluation, including Bacillus coagulans MY01, Bacillus subtilis MY02, ginger, peppermint, or antibiotics.
- Known allergy or hypersensitivity to any component of the investigational product.
- Contraindication or specific warning related to the investigational product, including use of anticoagulants.
- Use of immunosuppressive therapy within the last 3 months.
- Use of medications affecting gastrointestinal motility or sensitivity, including opioids, GLP-1 analogs, neuroleptics, antiemetics, or anticholinergics. (Stable antidepressant therapy allowed.)

... and 11 more (see full listing online)

Locations (1 total)

Gerard DASSA, Istres, France