

The effect of a probiotic compound in dyspeptic patients [Eficácia terapêutica de composto probiótico em pacientes dispépticos]

Submission date 28/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/05/2017	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Functional dyspepsia is a condition that causes an upset stomach or pain or discomfort in the upper belly, near the ribs. Probiotics are live bacteria and yeasts promoted as having various health benefits, which can be taken as food supplements. The aim of this study is to assess the effects of a probiotic in patients with functional dyspepsia.

Who can participate?

Patients aged between 18 and 80 with functional dyspepsia

What does the study involve?

Participants are randomly allocated to take either a probiotic, a probiotic with a lipidic (fat) emulsion (Fabules), or a placebo (dummy supplement). Blood samples are collected and functional dyspepsia symptoms are assessed in all three groups.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Instituto Central do Hospital das Clínicas (ICHC) (Brazil)

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

January 2012 to December 2012

Who is funding the study?

Brazil Foods (Brazil)

Who is the main contact?

Dr Ricardo Barbuti
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Contact information

Type(s)

Scientific

Contact name

Dr Ricardo Barbuti

Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Therapeutic efficacy of a probiotic compaond in dyspeptic patients: a randomised controlled trial

Study objectives

Functional dyspesia is the most common functional disease of the upper gastrointestinal (GI) tract, its prevalence is around 20-40% in the eastern population of Brazil. Functional dyspepsia is a disease whose physiopathology is dependent of gastric motility as well as gut microbiota. Probiotics can interfere wiith both. The chronic use of such supplements can improve dyspepsia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Universiy of São Paulo Ethics Commitee, 31/08/2011

Study design

Prospective randomized double-blind placebo-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Functional dyspepsia

Interventions

150 patients with functional dyspepsia will be divided into three groups:

1. Probiotic
2. Probiotic + lipid
3. Placebo

They will receive the products for 3 months, symptoms and biochemistry will be achieved before the study, in the end of the products supplementation and 3 months after stopping the products.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. The Short-Form Leeds Dyspepsia Questionnaire
2. Biochemistry of ghrelin and leptin levels

Key secondary outcome(s)

1. Adverse events
2. Compliance
3. Bowel habit
4. Body Mass Index (BMI)

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Must have diagnosis of functional dyspepsia (Rome III criteria)
2. Signed informed consent
3. Aged between 18 and 80

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Abdominal surgery
2. Major commorbidities that lead to use of drugs which can interfere with symptoms or modify gastric or bowel motility
3. Gastroesophageal reflux disease (GERD)
4. Active peptic ulcer disease (PUD)
5. Use of non steroidal anti inflammatory drugs (NSAIDs) or antibiotics
6. Gastrointestinal (GI) tract neoplasia
7. Pregnant women
8. History of yogurt intolerance or allergy

Date of first enrolment

15/01/2012

Date of final enrolment

31/12/2012

Locations**Countries of recruitment**

Brazil

Study participating centre

Instituto Central do Hospital das Clínicas (ICHC)

Sao Paulo

Brazil

05403-000

Sponsor information**Organisation**

Brazil Foods (Brazil)

ROR

<https://ror.org/05xv38e59>

Funder(s)**Funder type**

Industry

Funder Name

Brazil Foods (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration