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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	[_] Prospectively registered [_] Protocol
Registration date 31/01/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/05/2017	**Condition category** Digestive System	[_] Individual participant data [_] 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 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 (Fabuless), 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 motiliy 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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

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

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

Overall study start date
15/01/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

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)

Sponsor details
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Sponsor type
Industry

Website
http://www.brasilfoods.com/

ROR
https://ror.org/05xv38e59

Funder(s)

Funder type
Industry

Funder Name
Brazil Foods (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration