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# Association of a probiotic to a Helicobacter pylori eradication scheme does not increase eradication rate neither decrease the adverse events

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 11/01/2011 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 31/01/2011 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 12/09/2013 | Digestive System | |

**Plain English summary of protocol**
Not provided at time of registration

## 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
Association of a probiotic to a Helicobacter pylori eradication scheme does not increase eradication rate neither decrease the adverse events: a prospective, randomised double-blind placebo controlled study

### Study objectives
The Helicobacter pylori (Hp) eradication schemes have frequent adverse events, leading patients to interrupt the treatment. Consequently, therapeutic failure and bacteria resistance can develop. Proton pump inhibitor (PPI), furazolidone and tetracycline (PPI/F/T) is cheap, presents low bacteria resistance, has high eradication rates, but with many adverse events. Among these events, alterations in gut habits are the most important and secondary to changes in intestinal microflora due to antibiotic treatment. Probiotics are an excellent tool to control the bacteria overgrowing, helping prevent or decrease the adverse events consequent to antibiotics use.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics Committee of the Clinic of Hospital of the School of Medicine of the University of Sao Paulo approved on the 18/04/2007

### Study design
Prospective randomised double-blind placebo controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

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

### Health condition(s) or problem(s) studied
Peptic ulcer, functional dyspepsia

### Interventions
77 Hp positive patients without previous treatments to Hp were enrolled. Hp status was confirmed with at least two positive tests (urease, histologic or breath test with 14 carbon). Patients were divided in two groups:
1. Lansoprazole 30 mg, furazolidone 200 mg, tetracycline 500 mg twice daily (bid) and probiotic (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium bifidum and Streptococcus Faecium) (n = 40) for 7 days
2. Lansoprazole 30 mg, furazolidone 200 mg, tetracycline 500 mg bid and probiotic placebo (n = 37) for 7 days

The probiotic or probiotic placebo was maintained for 23 more days. All patients were clinically evaluated at initial visit, 7, 30 and 60 days. In the final visit the patients had the Hp eradication confirmed using at least two tests that had to be negative (urease, histologic or C14UBT). The following symptoms were investigated: epigastric pain, heartburn, nausea, vomiting, diarrhoea, bloating and abdominal pain. Each symptom was quantified using the following score: zero (without symptom), one (mild intensity), two (moderate intensity) and three (severe intensity).

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Lansoprazole, furazolidone, tetracycline, probiotic (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium bifidum and Streptococcus Faecium)

### Primary outcome measure
Treatment efficacy was determined by bacterial negativity in at least two diagnostic methods: rapid urease test, histological examination of gastric antrum and corpus mucosa samples or 14C urea breath test, performed 60 days after completion of the eradication treatment.

### Secondary outcome measures
1. Adverse effects
2. Compliance to treatment

### Overall study start date
20/04/2007

### Completion date
25/09/2010

## Eligibility

### Key inclusion criteria
1. Peptic ulcer disease or functional dyspepsia
2. H. pylori infected status was determined by concordance of the at least two biopsy-based diagnostic tests (rapid urease test, histology or 14C labeled urea breath test)
3. Aged 18 to 70 years, either sex

**Participant type(s)**
Patient

**Age group**
Adult

**Lower age limit**
18 Years

**Sex**
Both

**Target number of participants**
51 with peptic ulcer and 26 with functional dyspepsia

**Key exclusion criteria**
Previously treated Helicobacter pylori infection

**Date of first enrolment**
20/04/2007

**Date of final enrolment**
25/09/2010

# Locations

**Countries of recruitment**
Brazil

**Study participating centre**
**Hospital Clinic of the School of Medicine of the University of São Paulo**
São Paulo
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# Sponsor information

**Organisation**
Hospital Clinic of the School of Medicine of the University of São Paulo (Brazil)

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**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/036rp1748

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Hospital Clinic of the School of Medicine of the University of São Paulo (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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 26/03/2013 | | Yes | No |