

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
11/01/2011	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
31/01/2011	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
12/09/2013	Digestive System	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Tomas Navarro-Rodriguez

Contact details

Hospital Clinic of the School of Medicine of the University of São Paulo
Department of Gastroenterology - Clinical Gastroenterology
Av. Dr. Eneas Carvalho de Aguiar, 255
ICHG, 9th floor, Office 9159
São Paulo
Brazil
05403-000
+55 11 3069 7830
tomasnavarro@uol.com.br

Additional identifiers

Protocol serial number

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 São Paulo approved on the 18/04/2007

Study design

Prospective randomised double-blind placebo controlled trial

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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 ^{14}C urea breath test, performed 60 days after completion of the eradication treatment.

Key secondary outcome(s)

1. Adverse effects
2. Compliance to treatment

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 ^{14}C labeled urea breath test)
3. Aged 18 to 70 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Brazil

05403-000

Sponsor information

Organisation

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes