Author's response to reviews

Title: Association of a probiotic to a Helicobacter pylori eradication regimen does not increase efficacy or decreases the adverse effects of the treatment: a prospective, randomized, double-blind, placebo-controlled study.

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Author's response to reviews: see over
Dear Editor

As you requested, we are sending the files with the approval by the Ethics Committee of our Institution.

We have point out in the text the name of the committee, in Methods – Patients: “Ethics Committee for Analysis of Research Projects - CAPPesq – of the Clinical Board of Clinics Hospital, Faculty of Medicine, University of Sao Paulo”

It is also presents details of the sample population to work, in section Methods – Patients: “Developed in 2007, the study design didn’t have previous data in literature, for the proposed regimen: Associate at 7 days of treatment to H. pylori eradication, 7 days +23 of probiotic. The sample calculation was based on a previous study[18] with a similar regimen, in which 20 mg of omeprazole was taken once a day, with tetracycline 500 mg and furazolidone 200 mg three times daily, for 7 days. The eradication efficacy was 75% and the prevalence of adverse effects 34%, with 15% of severe adverse effects. It was considered sufficient to allocate 60 patients to active probiotic and 60 to placebo probiotic.”

We have prepared, according to the CONSORT 2010 model, the flow diagram of patient enrollment in the study (Probiotic Flow Diagram - Figure 2), referred to item Results - Data from the population included: “The flow diagram of patient enrollment in this study is shown in Figure 2”
Figure 2. – Probiotic Flow Diagram

Assessed for eligibility (n=120)

Not meeting inclusion criteria (n=13)

Randomized (n=107)

Allocated to active probiotic (n=55)
Received allocated intervention (n=55)

Allocated to placebo probiotic (n=52)
Received allocated intervention (n=52)

Follow-Up

Lost to follow-up (n=1) refused medication
Discontinued intervention (n=3) noncompliance

Included in analysis (n=51)

Included in analysis (n=49)

Allocation

Analysis

Included in analysis (n=49)