

STUDY FACTS

High Effective of 14-Day High-Dose PPI-Bismuth-Containing Quadruple Therapy with Probiotics Supplement for *Helicobacter Pylori* Eradication: A Double Blinded Randomized Placebo-Controlled Study

Principal Investigator

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Study objective

Bismuth-containing quadruple therapy is the first line treatment recommended for *H. pylori* infection in many European countries. However, evidence of the efficacy in many Asian countries is limited, especially in Thailand.

The aim of this study was to evaluate the efficacy of high-dose PPI and bismuth-containing quadruple therapy combined with a probiotic supplementation (*Lactobacillus reuteri* Gastrus) in *H. pylori* eradication.

Study design

Double-blind, randomized, placebo-controlled study which enrolled 100 patients (72 females and 28 males, mean age of 54 years) divided into four groups. All patients received high-dose PPI and a bismuth-containing quadruple therapy. Patients in group I were treated for 7 days and were additionally supplemented by *Lactobacillus reuteri* Gastrus (2×10^8 , twice daily), whereas group II received a placebo. Group III was treated for 14 days and supplemented by *Lactobacillus reuteri* Gastrus, whereas group IV received placebo instead of the probiotic.

Outcome parameters

Primary outcome was eradication of *H. pylori*, defined as a negative ¹³C-urea breath test at least four weeks after treatment.

Results

The eradication rate was 68% in the group treated with quadruple therapy and supplemented by *Lactobacillus reuteri* Gastrus for 7 days. Equivalent figure for the placebo group was 72%. In the groups treated for 14 days the eradication rate was 96% for those supplemented by *Lactobacillus reuteri* Gastrus and 88% for placebo. There were no significant differences between the groups.

Supplementation with *Lactobacillus reuteri* Gastrus significantly reduced treatment-related side-effects; incidence of nausea and vomiting, abdominal pain, and bitter taste.

Conclusions

The 14-day high-dose PPI and bismuth-containing quadruple therapy combined with a *Lactobacillus reuteri* Gastrus can provide excellent cure rate for *H. pylori* infection as first line treatment. Supplementation of *Lactobacillus reuteri* Gastrus also significantly reduced treatment-related adverse events and improved the patients' compliance.

