P.O. Box 144345 Austin, TX 78714-4345 ▪ 512.926.4900 ▪ Fax: 512.926.2345 ▪ www.herbalgram.org

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File: ■ Licorice (*Glycyrrhiza glabra*)
■ *Helicobacter pylori*
■ GutGard®

HC 091381-490

Date: February 14, 2014

RE: GutGard®, a Licorice Extract, Aids in the Management of *Helicobacter pylori*

Puram S, Suh HC, Kim SU, et al. Effect of GutGard® in the management of *Helicobacter pylori*: A randomized double blind placebo controlled study. *Evid Based Complement Alternat Med*. 2013;2013:263805. doi: 10.1155/2013/263805.

Helicobacter pylori (*H. pylori*) are a helical-shaped gram-negative bacteria inhabiting gastric epithelial cells of half the world's population. Presence of the bacterium is associated with increased risk of developing peptic ulcer disease, gastric cancer, and gastric MALT lymphoma. With the increasing prevalence of resistance to antibiotics, herbal supplements have been explored as an alternative for the management of *H. pylori*. A randomized double-blind, placebo-controlled study on GutGard® (Natural Remedies; Bangalore, India), a deglycyrrhizinated extract of licorice (*Glycyrrhiza glabra*), was conducted to evaluate its efficacy in the management of *Helicobacter pylori* gastric load.

Investigators at D2L Pharma Research Centre, Bangalore, Karnataka, India, conducted the trial from July 2011 to November 2011 in subjects, aged between 18-45 years, with positive response to *H. pylori* stool antigen test (HpSA) and ^{13}C-urea breath test (^{13}C-UBT). Subjects were excluded if they had a history of bleeding duodenal ulcer, MALT lymphoma, gastroesophageal reflux, surgery for ulcers, or had advanced chronic illness, mental illness, dementia, or were suffering with concomitant symptoms of irritable bowel syndrome. Also, subjects taking antibiotics and/or proton pump inhibitors (PPIs) and/or H_2-antagonists 2 weeks prior to the administration of the investigational product or who were using non-steroidal anti-inflammatory drugs, steroids, bismuth preparation, or were alcohol and drug abusers were excluded. First-level relatives to patients with gastric cancer and pregnant or lactating women were also excluded.

A total of 100 subjects randomly assigned to GutGard (n = 50) or placebo (n = 50) completed the study. Each subject was either administered GutGard (150 mg) or placebo, 1 capsule in the morning before food, for a period of 60 days. GutGard is a flavonoid-rich root extract of licorice and has the following phytochemical specifications: glabridin (≥3.5% per weight), glabrol (≥0.5% per weight), eicosanyl caffeate (≥0.1% per weight), docosyl caffeate (≥0.1% per weight), glycyrrhizin (≤0.5% per weight), and total flavonoids (≥10% per weight).

The gastric *H. pylori* load in the subjects was assessed using ^{13}C-UBT and HpSA test at days 0, 30, and 60. The proportion of subjects with initial positive ^{13}C-UBT and HpSA test results found to be negative at day 30 and day 60 were assessed. Repeated measures of analysis of variance, chi-square, and Fisher's exact probability tests were used to analyze the treatment outcomes.

At baseline, all subjects were diagnosed to be positive for *H. pylori* in ^{13}C-UBT and HpSA test. There were no significant differences between the mean demographic characteristics of placebo and GutGard-treated groups. A significant interaction effect between group and time (P = 0.00) and time effect (P = 0.00) were observed between the groups. Significant difference in mean delta over baseline (^{13}C-UBT results expressed as delta over baseline) values was observed between GutGard and placebo-treated groups after the intervention period (P = 0.02). At day 30, all placebo and treated patients remained positive for ^{13}C-UBT and HpSA test. At day 60, 28 (56%) subjects in the GutGard-treated group showed a negative response to the HpSA test, and 24 (48%) subjects showed a negative response to ^{13}C-UBT, compared to 2 (4%) and 1 (2%), respectively, for the placebo group. The differences between the proportion of subjects who showed a negative response to ^{13}C-UBT and the HpSA test in GutGard and placebo-treated groups were statistically significant. The frequencies of adverse side effects in GutGard and placebo-treated groups were comparable and non-significant.

The authors conclude that GutGard is both safe and effective in the management of *H. pylori*. This provides a potential option to antibiotic monotherapy. Further study is warranted in subjects who are antibiotic-resistant or in combination with antibiotics and/or PPIs.

Referenced article can be found at www.hindawi.com/journals/ecam/2013/263805.