

Herbal Drug Rivals PPIs in Breakthrough Clinical Trial

Results from a breakthrough clinical trial investigating the efficacy and tolerability of treatments for functional dyspepsia (FD) have revealed that the natural medicine Iberogast worked as well as a proton pump inhibitor (esomeprazole), with less chance of symptoms recurring after stopping treatment.

The results were presented at DDW (Digestive Disease Week), the international gastroenterology congress, in Orlando, Florida in May 2013 by the principle investigator of the trial, Prof Gerald Holtmann, Director of the Department of Gastroenterology and Hepatology at the Princess Alexandra Hospital in Brisbane, Australia.

Iberogast is the only medicine indicated for both irritable bowel syndrome (IBS) and FD in Germany and the only complementary medicine approved for efficacy and safety in IBS and FD by Australia's TGA (Therapeutic Goods Administration). In South Africa, doctors' prescriptions are dispensed in pharmacies, with patients being reimbursed by the majority of medical schemes.

Study results

Funded by an Australian government grant, the trial involved 110 patients with FD who were divided into four arms



Professor Gerald Holtmann, principal investigator.

enabling comparisons between placebo, Iberogast, PPI (esomeprazole), and Iberogast combined with PPI.

- The clinical trial revealed that after four weeks of treatment, Iberogast worked as well in reducing symptoms of FD as a PPI, with both being significantly better than placebo (p<0.05).
- Of particular note, is the fact that relapse rates after cessation of active therapy for two weeks, were significantly higher with the PPI (47%, n=19) compared to Iberogast (7%, n=15), especially for symptoms such as heartburn and abdominal pain.
- Furthermore, the clinical trial showed that combining a PPI and Iberogast did not yield a better response rate, and that relapse rates after using the combined mixture were higher compared to using Iberogast alone (58%, n=12).

Prof Holtmann commented that "The result is significant, as it shows for the first time, that when studied for efficacy and safety, there is no statistical difference in efficacy of natural medicines and mainstream drugs.

"What is interesting about this study is that it gives consumers, who experience often debilitating gastrointestinal symptoms, the comfort and confidence that there are clinically proven natural options outside of prescription medications.

"The fact that Iberogast has been used for over 50 years around the world is now reinforced by the results of this study."

Iberogast is a liquid formulation combining nine herbal extracts that work synergistically to provide relief from the symptoms of both IBS and dyspepsia. The herbs included in Iberogast are angelica root, caraway fruit, celandine, liquorice root, bitter candy tuft, chamomile, lemon balm, peppermint and St Mary's thistle.

Widely used, extensively tested

Used by an estimated 25 million people worldwide, Iberogast has been studied in 19 clinical trials, seven of which were double blind and randomised. Since its launch, no significant adverse medical reactions have been reported to drug regulatory authorities worldwide.

Iberogast binds to 5-HT₃, 5-HT₄, muscarinic M₃ and opioid receptors in the gut. Results from clinical trials indicate that Iberogast reduces symptoms in patients with FD and IBS by normalising dysfunctional gastrointestinal motility, toning the lower oesophageal sphincter, reducing the production of gastric acid, reducing visceral hypersensitivity and demonstrating anti-inflammatory properties in the gut. These five actions work together to reduce the gastrointestinal symptoms associated with IBS and FD including bloating, cramping, constipation, reflux, flatulence, abdominal pain, diarrhoea, nausea and stomach pain.

References:

- 1. Wang WH et al Clin Gastro & Hepato 2007;5 178-185.
- 2. Gundermann, KJ et al Advances in Natural Therapy 2003; Vol 20 (1) Jan-Feb; 43-49.
- 3. A Placebo Controlled Randomised Treatment Trial for Functional Dyspepsia including Post-Treatment Drug Withdraw and Placebo Withdraw Effects. Holtmann, G et al Digestive Disease Week 2013, Orlando, USA, Abs M02071



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> IBS: Irritable Bowel Syndrome. References: 1. Madisch A, et al. Aliment Pharmacol Ther. 2004;19:271-9. 2. Rösch W, et al. Z Gastroenterol. 2002;40:401-8. 3. Gundermann K-J, et al. Adv Ther. 2003;20:43-9. 4. Malfertheiner P, et al. GI-Telex. Supplement for Gastroenterologists. 2011;2:1-8.



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