UEG Week 2015 - Abstract Submission

Topic area: 5. NUTRITION

Topic: 5.2. Nutrients and gut function

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THE COMBINATION OF RETICULATED VEGETABLE PROTEIN AND OLIGO- AND POLY-SACCHARIDES (GELSECTAN®) FOR THE CONTROL OF SYMPTOMS OF PATIENTS WITH IRRITABLE BOWEL SYNDROME: RESULTS OF A RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND, MULTICENTRE CLINICAL TRIAL

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Introduction: There is a strong rationale for the use of reticulated proteins and oligo- and poly-saccharides in irritable bowel syndrome (IBS), although few data exist from clinical trials.

Aims & Methods: To evaluate the safety and efficacy of Gelsectan® tablets (containing 300 mg of oligo- and poly-saccharides and 250 mg of reticulated vegetable protein), in comparison with placebo in adult patients with diarrhea-predominant IBS.

This randomized, placebo-controlled, double-blind, parallel group, multicentre, clinical trial was performed to evaluate the safety and efficacy of Gelsectan® tablets (containing oligo- and poly-saccharides and reticulated vegetable protein, 4 tablets/day during 8 weeks), in comparison with placebo (tablets) in adult patients with diarrhea-predominant IBS (according to Rome III criteria).

At visit 1, baseline characteristics were recorded and patients were instructed to fulfill a patient´s diary card to daily register treatment, adverse events, number and type of stool emissions and the use of rescue medication.

Assessment of quality of life, using the IBS QoL questionnaire, physical examination and blood sampling were performed at visits 1 and 3 (at 8 weeks). During visits 1, 2 (at 4 weeks) and 3, patients measured the presence and intensity of abdominal pain and flatulence in a 7-point Likert scale.

Results: A total of 128 Caucasian patients of them were randomized to receive either Gelsectan® tablets (n=63) or placebo (n=65). Demographic, clinical and analytical characteristics were homogeneous in both groups, with more women than men (69.35% vs 30.65%) and with a mean age around 48 years.

Both treatments were safe and well tolerated, with a decrease in the occurrence of adverse events at visit 3 (4 events in Gelsectan® and 5 in the placebo group, p=0.0361).

We observed a statistically significant increase in the rate of clinical remissions across the study in the active group (66.6% at visit 2 and 76.19% at visit 3) ($p<0.0001$ among visits, Kruskall Wallis test). We also detected a significant improvement in symptoms across the study in patients treated with Gelsectan®, with statistically significant differences between visit 2 and visit 3 in abdominal pain (p=0.0167) and flatulence (p=0.0373).

We also detected a statistically significant increase in the quality of life of patients receiving Gelsectan® tablets from baseline to visit 3 ($p<0.0001$).

Conclusion: Gelsectan® tablets are safe and well tolerated, being to improve IBS symptoms and quality of life in patients with diarrhea-predominant IBS.

I confirm having declared any potential Conflict of Interest for ALL authors listed on this abstract: Yes

Disclosure of Interest: None Declared

Keywords: efficacy, irritable bowel syndrome, mucosal protectors, polysaccharides, protein, quality of life