**Abstract:**

Objective: Diarrhea predominant irritable bowel syndrome (IBS-D) is a common, chronic illness characterized by recurrent abdominal pain and loose or watery stools. Current treatment options include fiber supplements, dietary modifications, and laxatives. Oral ondansetron was evaluated in a double-blind, placebo-controlled, 28-day trial for treatment of IBS-D.

Method: A total of 253 patients with IBS-D were randomized to receive ondansetron (BRO) 4 mg twice daily or placebo (PBO) for 28 days. Primary end points were bowel frequency, stool consistency, abdominal pain intensity, and composite response (CRC). A CRP parameter analysis was performed in a post hoc manner to evaluate a potential predictor of treatment effect. Baseline CRP was stratified by gender and randomized 60:40 to RHB-102 and Placebo, respectively.

Results: At the end of treatment, patients treated with ondansetron (BRO) had statistically significant improvements over Placebo (PBO) for bowel frequency (p<0.001), stool consistency (p<0.001), and composite response (p=0.008). A post hoc analysis of CRP revealed a trend towards improvement in response at 28 days in patients with higher CRP on entry (p=0.036). No new safety signals were identified.

Conclusion: Ondansetron was active in both males and females. Further study of baseline CRP is warranted.

**Methodology:**

- **Study design:** Double-blind, placebo-controlled, 28-day trial
- **Participants:** 253 patients with IBS-D
- **Endpoints:** Bowel frequency, stool consistency, abdominal pain intensity, and composite response
- **Treatment:** Ondansetron (BRO) 4 mg twice daily, Placebo (PBO)
- **Analysis:** Baseline CRP was stratified by gender and randomized 60:40 to RHB-102 and Placebo, respectively
- **Results:** Ondansetron had statistically significant improvements over Placebo for bowel frequency, stool consistency, and composite response. A post hoc analysis of CRP revealed a trend towards improvement in response at 28 days in patients with higher CRP on entry. No new safety signals were identified.

**Conclusion:** Ondansetron was active in both males and females. Further study of baseline CRP is warranted.