

Introduction:

Irritable bowel syndrome with constipation (IBS-C) is a complex functional gastrointestinal disorder. This trial investigated the efficacy and safety of a non-pharmacological formula with xyloglucan, pea protein and chia seed powder in IBS-C patients.

Methods:

IBS-C patients were randomised to receive a test formula or placebo twice daily for 28 days (Period 1) and crossed over to the alternative intervention for another 28 days (Period 2) after a washout period (28 days). Symptom severity [Likert scale, visual analogue scale (VAS)], stool consistency (Bristol stool form scale), patients' quality of life (IBS-QoL questionnaire), intestinal permeability (serum zonulin) and adverse events were monitored and analysed.

Results:

Sixty adult patients were enrolled and completed the study. Findings demonstrated the ability of the test formula to relieve IBS symptoms. Significant reduction in discomfort, abdominal pain and bloating rated by the Likert scale in the test formula group was observed at the end of both Periods 1 and 2, compared to placebo ($p < 0.001$ in each comparison). Moreover, the test formula was superior to the placebo in resolving constipation, as rated by the Bristol stool form scale. All patients reported constipation at baseline: those taking the test formula reported normal stools at the end of Period 1 (Day 28), while those in the placebo group showed no improvement. Similar results were recorded at the end of Period 2. Serum zonulin, a biomarker of intestinal permeability, was significantly reduced by the test formula (Days 28, 84, $p < 0.001$) compared to placebo, suggesting a potential restoration of intestinal permeability. Additionally, the test formula demonstrated significant improvement in patients' quality of life, indicated by significantly increased IBS-QoL scores at Days 15, 28 and 84 versus placebo ($p < 0.001$). The test formula was well-tolerated. No serious adverse events or allergic reactions were reported during the study period.

Conclusions:

For the first time, a combination of xyloglucan, pea protein and chia seed powder was clinically proven to be efficacious and safe for IBS-C patients, showing a significant improvement in stool consistency, symptom severity and patient's quality of life together with potential restoration of intestinal permeability indicated by serum zonulin.