Among adult patients diagnosed with IBS, a sizable proportion suffer from a mixed bowel habit life.3 There is no FDA approved therapy for IBS-M and it remains an unmet medical need. The IBG12-17R1 and IBS-M patients.

IBSREST* trial. This trial had already shown favorable results in a combined group of IBS-D and IBS-M, an analysis was performed on the effects of PO-SST among patients with IBS-M in the IBG12-17R1 trial. This trial had already shown favorable results in a combined group of IBS-D and IBS-M patients.

To determine whether PO-SST would be a possible treatment option for patients with IBS-M, a trial was performed. Subjects met Rome III criteria for IBS-M, had average daily IBS related abdominal pain of ≥ 4 on a 0-4 scale. Subjects were randomly allocated to receive PO-SST (81 mg TID) or identical placebo for 4 weeks. Primary analysis was based on the TISS score. Additional assessments included change from baseline in frequency and intensity of individual IBS symptoms.

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The number of IBS-M participants in the PO-SST group was 16 and the number of IBS-M participants in the placebo group was 18.

Methods

Subjects met Rome III criteria for IBS-M, had average daily IBS related abdominal pain of ≥ 4 on a 0-4 scale, and a TSS of ≥ 2 on a 0-4 scale. Subjects were randomly allocated to receive PO-SST (81 mg) or identical placebo for 4 weeks. Primary analysis was based on the TISS score. Additional assessments included change from baseline in frequency and intensity of individual IBS symptoms.

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Results

After 4 weeks of treatment, the PO-SST arm demonstrated statistically significant reduction versus placebo in both constipation (P=0.0221), urgency (P=0.04), and sense of incomplete evacuation (P=0.03) with near-significance (P=0.053) in the intensity of IBS symptoms (Figure 2).

Figure 4. Individual symptom frequency and intensity after 4 weeks for patients with IBS-M

Conclusions

Figure 5. Constipation score, frequency, and intensity in patients with IBS-M

References

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Disclosures

PO-SST is an option for IBS-M, a common IBS subtype, where no approved therapies exist

Figure 3. Individual symptom frequency and intensity after 4 weeks for patients with IBS-M

% Average Difference in Symptoms Score

Notes:

• To add to the current data that PO helps to relieve symptoms of IBS-D and IBS-C, as was shown in an earlier RCT5
• To determine whether PO-SST would be a possible treatment option for patients with IBS-M

Figure 2. Total IBS symptom score after 4 weeks for patients with IBS-M

Figure 1. Immune activation and epithelial cell death in a dysfunctional gut versus a functional gut.

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Gut barrier dysfunction

• Gut mucosal barrier dysfunction is a significant contributor to symptoms of IBS-M.

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