IgG-based Elimination Diets for Patients with IBS: Results From a Prospective, Multi-Center, Double-Blind, Placebo-Controlled Trial

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Introduction

Diet modification can improve symptoms in patients with IBS, however, outcomes following self-directed elimination diets are poor. Food intolerances/ sensitivities are common in patients with IBS but the role of IgG antibodies in identifying patients with food sensitivities is controversial. This study was designed to evaluate the utility of a novel, proprietary IgG-based elimination diet to improve symptoms in IBS patients. ClinicalTrials.gov Identifier: NCT03459482

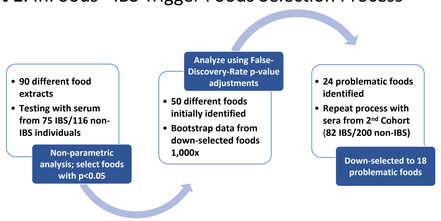
Methods and Materials

Adults with IBS (Rome IV), all subtypes, were enrolled from 6 centers into a 2-week baseline period. Patients who tested positive ≥1 food in an IgG panel (inFoods®, Biomerica, Irvine, CA) and who reported an average daily IBS abdominal pain intensity (API) score (0-10) between ≥3 and ≤7.5 were randomized to either a treatment diet arm or a sham (placebo) diet arm for 8 weeks. Patients in the treatment diet arm were instructed to eliminate foods to which they tested positive. Patients in the sham diet arm were instructed to eliminate foods to which they tested negative. The sham diet arm was balanced to the treatment diet arm with respect to the number of foods eliminated and self-reported frequency of consuming a particular food. Daily assessments included bowel habits, bloating, and API, as well as weekly assessments for IBS Adequate Relief (AR), Subject Global Assessment of Relief (SGA), and Global Improvement Scale (GIS). Linear mixed and logistic regression modeling of endpoints in the intent-to-treat (ITT) population is presented for all IBS patients and for non-IBS-D patients.

Background

InFoods® IBS is unique in that the panel of foods and cutoffs for positive and negative results are specific for IBS patients. (See Chart 1) Briefly, 90 different food extracts were tested with confirmed ROME III positive IBS patient samples and confirmed non-IBS, non-GI disease patient samples. Using non-parametric statistical analysis, 50 foods with unadjusted p-values of <0.05 for increased IgG values in IBS patients (vs. non-IBS patients) were identified. Data were then bootstrapped 1,000 times and further analyzed using False-Discovery-Rate (FDR) p-value adjustments. Multiple cohorts were then analyzed. As a result, 18 foods were selected for the assay. Cutoff values were set using a 95% confidence interval for each food.

Chart 1. InFoods® IBS Trigger Foods Selection Process



Results

Of the 556 patients with IBS (all subtypes) who entered the study, 223 met eligibility criteria and were randomized to the treatment diet or sham diet. IBS patients in the treatment diet arm had a greater decrease in IBS-API and IBS-Bloating scores from baseline compared to patients in the sham diet arm (IBS-API p=0.0718; IBS-Bloating p=0.0827, these p-values did not reach the threshold of p< 0.05). However, patients in the treatment diet arm did have a significant improvement in GIS and SGA (GIS p=0.0302; SGA p=0.0093) compared to the sham diet arm. Non-IBS-D patients (i.e., IBS-C + M) (n=149) had the greatest decrease from baseline (IBS-API p=0.0139; IBS-Bloating p=0.0214) as well as for global measures (GIS p=0.0020;SGA p=0.0010). No significant adverse events were noted during the study.

Chart 2. Patient Demographics

Starting with a pool of 556 IBS patients, 238 met the screening criteria and were randomized into the trial

·Mean age 41
-21.5% Male
-78.5% Female
- 93.4 is the mean number of months patients were treated for IBS prior to enrollment in the trial

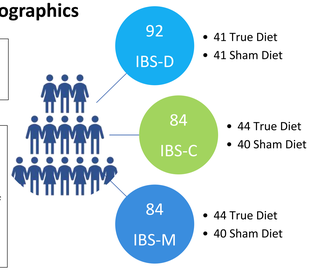


Table 1. p-value Key Assessment Criteria

Baseline to 8 weeks p-value				
	All Subj	IBS-C	IBS-M	IBS-C+M
API (Lin. Mix. Model)	0.0718	0.0256	0.1200	0.0139
Bloating (LMM)	0.0827	0.1200	0.0900	0.0214
SGA (LMM)	0.0093	0.0100	0.0154	0.0010
GIS (LMM)	0.0302	0.0090	0.1200	0.0020
IBS-SSS (LMM)	0.1100	0.2300	0.3600	0.1400
AR logistic mixed model	0.0600			
API 30% improvement	0.0246 p-value	10% difference between treatment and placebo (15% female only)		
IBS-SSS 50pt improvement	0.13 P-value	IBS SSS Responder		

Results

Figure 1. API IBS non-D Population Change from Baseline

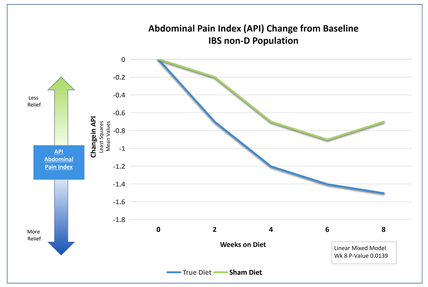


Figure 2. Bloating IBS non-D Population Change from Baseline

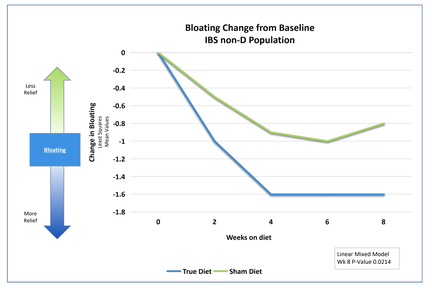
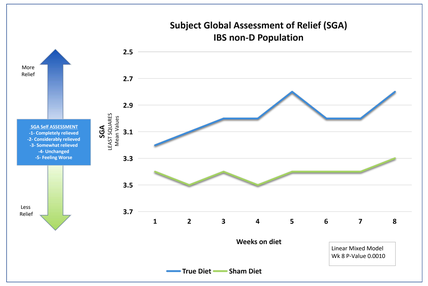


Figure 3. SGA Relief IBS non-D Population Change from Baseline



Results

Figure 4. GIS IBS non-D Population Change from Baseline

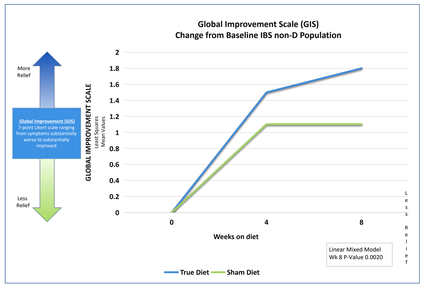


Figure 5. SGA IBS All Population Change from Baseline

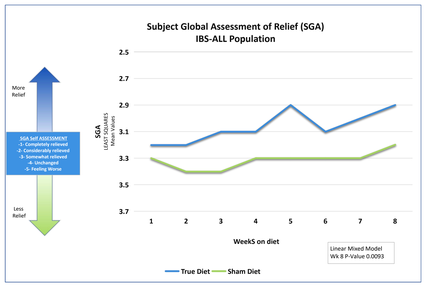
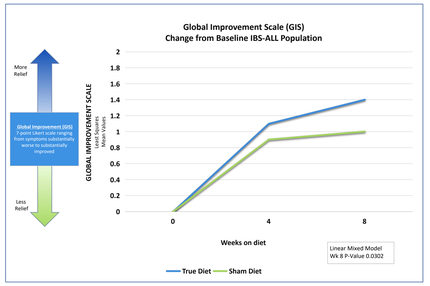
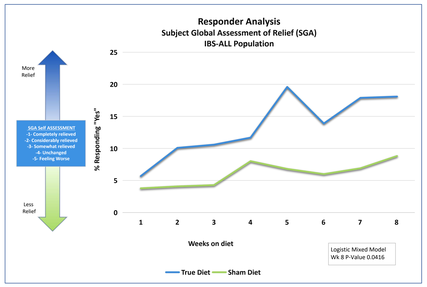


Figure 6. GIS IBS All Population Responder Relief



Results

Figure 7. SGA IBS All Population Responder Relief



Discussion

These results suggest that IgG based elimination diets using a novel, proprietary diagnostic (inFoods® IBS) with 18 specific foods to guide therapy may offer benefit to patients with IBS.

Results of this study warrant further study.

Conclusions

A novel IgG based elimination diet in comparison to a sham diet significantly improved global endpoints (both GIS and SGA) and showed a trend for improvement in IBS-API (p=0.0718) and IBS-Bloating (p=0.0827) in all IBS subtypes.

Non-IBS-D (IBS-C + M) patients in the treatment diet arm had significant individual symptom relief for abdominal pain (p=0.0139) and bloating (p=0.0214).

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References

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