

Study Protocol

Official Title: The Effect of a Low-FODMAP Diet on Leaky Gut, Symptoms, and Quality of Life in Patients with Irritable Bowel Syndrome

NCT Number: (to be added after registration)

Document Date: March 2026

Background

Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder characterized by recurrent abdominal pain and altered bowel habits. Dietary interventions, particularly the Low-FODMAP diet, have been shown to improve symptoms in IBS patients. The impact of this diet on intestinal permeability ("leaky gut") remains unclear.

Objective

To evaluate the effect of a Low-FODMAP diet on intestinal permeability, symptom severity, and quality of life in patients with IBS.

Study Design

Prospective, randomized, single-blind clinical study conducted at Istanbul Medipol Mega University Hospital between December 2023 and December 2024.

Participants

Adults aged 18–65 years diagnosed with IBS according to Rome IV criteria presenting to Internal Medicine or Gastroenterology outpatient clinics.

Interventions

Participants are randomized into two groups:

1. Low-FODMAP diet group
2. Traditional diet group

Dietary adherence is monitored through weekly diet diaries and consultations with a dietitian.

Outcome Measures

Primary outcomes include changes in IBS Symptom Severity Score (IBS-SSS).

Secondary outcomes include changes in IBS Quality of Life (IBS-QOL) scores and fecal zonulin levels.

Follow-up

Measurements are performed at baseline, week 4, and week 16 (for the Low-FODMAP group after gradual food reintroduction).

Statistical Analysis

Data will be analyzed using SPSS version 27. Continuous variables will be reported as mean \pm standard deviation or median values. Appropriate parametric or nonparametric tests will be used depending on data distribution. Statistical significance will be set at $p < 0.05$.

Ethics

The study protocol was approved by the Istanbul Medipol University Non-Interventional Clinical Research Ethics Committee. Written informed consent was obtained from all participants.