Clinical Study Synopsis – Cover Page

Official Title:
Effects of Partial Enteral Nutrition on Weight Loss and Sarcopenia in Patients with IBD at Risk of Caloric-Protein Malnutrition

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Confidentiality Notice:
This document does not include any names of research participants.

Document Summary:
This document provides the synopsis of the clinical study, including:

- Background and rationale
- Study objectives and endpoints
- Study design and treatment
- Eligibility criteria (inclusion and exclusion)
- Study procedures and visits
- Statistical analysis plan
- Study duration and sample size considerations

Study Title

Effects of Partial Enteral Nutrition on Weight Loss and Sarcopenia in Patients with IBD at Risk of Caloric-Protein Malnutrition

Version: 2.0 del 10/06/2025

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Study Type: Interventional nutritional study (non-pharmacologic), controlled, two-arm, multicenter

Condition / Disease: Inflammatory Bowel Disease (IBD)

Number of Participants: 146 participants (73 per arm; 124 evaluable subjects, 62 per arm, plus 15% drop-out anticipated per arm)

Number of Centers: 4

Background and Rationale

Inflammatory Bowel Diseases (IBD), including Crohn's disease (CD) and ulcerative colitis (UC), are chronic immune-mediated disorders with relapsing–remitting course. Standard therapeutic approaches include mesalazine, corticosteroids, immunosuppressants, antibiotics, biologics, and small molecules. Surgical intervention may be required in cases of pharmacological treatment failure (1–3).
Patients with IBD, particularly CD, often develop malabsorption of vitamins (B12, D) and minerals (Ca, Fe), anemia, hypocalcemia, hypomagnesemia, coagulation disorders, and bone demineralization. Malnutrition affects about one-third of patients in clinical remission (3, 12, 16, 18).
Malnutrition negatively impacts quality of life, response to therapy, hospitalization risk, and need for surgery. Pediatric patients may show impaired growth (4). ESPEN recommends regular nutritional follow-up for IBD patients, with joint evaluation by gastroenterologist and clinical nutritionist (3, 20).
The Malnutrition Universal Screening Tool (MUST) is widely used to assess malnutrition risk. Other assessments include NRS-2002, Mini Nutritional Assessment, BMI, anthropometry, skinfold thickness, BIA/BIVA, and handgrip dynamometry (17).
High-risk patients may receive specific dietary regimens or FSMP supplementation (3, 20). Evidence for FSMP-based interventions on weight and disease activity in IBD remains limited.

Objectives and Endpoints

Primary Objective:

- Evaluate maintenance and/or recovery of body weight following administration of LH VIOLA at 16 weeks.

Secondary Objectives:

- Evaluate weight maintenance/improvement at 24 weeks (T5) (>1 kg difference).
- Assess muscle recovery/preservation via handgrip strength.
- Evaluate metabolic recovery via body composition (BIA/BIVA) and serum levels of B12, D, prealbumin.
- Assess health-related quality of life (SF-12).
- Describe economic impact (direct/indirect costs).
- Assess adherence to LH VIOLA (>50% intake considered acceptable).
- Evaluate gastrointestinal tolerability.
- Assess malnutrition risk reduction via MUST score.

Eligibility Criteria

Inclusion Criteria:

- Confirmed Crohn's disease or UC
- MUST screening indicates malnutrition risk
- Age 18–65
- Informed consent
- Women of childbearing potential must use contraception

Exclusion Criteria:

- Current Crohn's Disease Exclusion Diet (CDED)
- Hospitalization
- Pregnancy
- Need for hypoproteic diet

Study Design and Treatment

Prospective, randomized, multicenter, open-label, interventional nutritional study (non-pharmacologic), 146 patients, 73 per arm. Total study duration: 18 months. Participation per patient: 24 weeks.

Treatment Arms:

1. Nutritional counseling without enteral support
2. Nutritional counseling with LH VIOLA oral enteral support (FSMP) for 16 weeks, minimum daily dose 412 kcal, dose individualized at T0.

Study Procedures and Visits

- Screening visit
- Baseline hospital visit (T0)
- Telephone follow-up (T1) – product initiation
- Second hospital visit (T2)
- Second telephone follow-up (T3)
- Third hospital visit (T4 – Week 16, end of intake)
- Final follow-up visit (T5 – Week 24)

Statistical Analysis Plan

Primary endpoint: maintenance or increase in body weight at 16 weeks.
Hypothesis: proportion achieving improvement increases from 40% (counseling alone) to 65% (LH VIOLA group).

Sample Size Determination

- 124 subjects (62 per arm) needed to detect difference, alpha = 5%, power = 80%
- Accounting for 15% dropout → total 146 subjects (73 per arm)

Study Duration

- Total study duration: 18 months (12 months enrollment + 6 months follow-up)
- Product intake: 16 weeks per patient
- Final follow-up: 24 weeks