CLINICAL EVIDENCE

Impact of a Concentrated High-Protein, High-Calorie Oral Nutritional Supplement with a Unique Blend of Fast- and Slow-Acting Proteins on Patient Outcomes

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Objective

The **primary objective** of this study was to evaluate the **effectiveness of a novel concentrated high-protein, high-calorie oral nutritional supplement** (cHPHC-ONS) in patients with disease-related malnutrition (DRM) or at high risk of malnutrition and sarcopenia and AI-supported morphofunctional assessment to monitor clinical outcomes (PI 22-2559*)

Materials and Methods:

This prospective, observational, single-arm study included **adults at risk of malnutrition**, identified using the MUST tool.

Participants received personalized nutritional interventions, for 3 month.

The **intervention** included **dietary counseling** and a concentrated high-protein, **high-calorie oral nutritional supplement** (≥2.1 kcal/mL and 32g of protein per 200mL) featuring **a blend of fast- and slow-acting proteins** (60% whey protein and 40% casein)** (Nestlé Health Science).

Assessments were conducted at baseline and after three months, including anthropometric measurements, BIA, muscular ultrasonography (US), handgrip strength, and laboratory parameters. An artificial intelligence (AI)-based software was used to assess muscle mass and quality as part of the morphofunctional assessment.

Study Variables:

The study collected demographic and clinical data, along with nutritional assessments. These included anthropometric measurements (Body weight, BMI, arm and calf circumference), BIA for impedance components, muscle US on the rectus femoris using AI-based imaging, handgrip strength, and biochemical parameters (albumin, prealbumin, CRP, CRP/prealbumin ratio, and creatinine).

Study Endpoints:

The **primary endpoint** was the percentage of weight loss after three months of cHPHC-ONS administration.

Secondary endpoints included changes in BIA and muscle US parameters, compliance with prescribed doses, and changes in malnutrition and sarcopenia prevalence, diagnosed according to GLIM and EWGSOP2 criteria, respectively.

* The study was independently conducted and reported objectively, with funding from Nestlé Health Science solely for hiring a medical writer and covering publication costs, without influencing the study's protocol, execution, or analysis

Results:

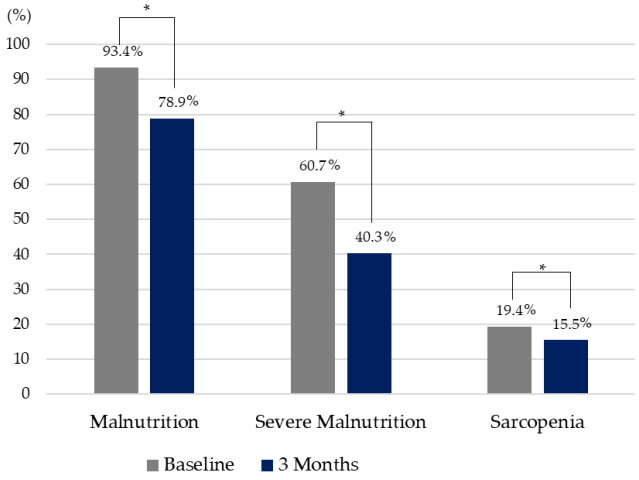
A total of **65 patients** participated, with a mean age of 59.35 years and a female predominance (63.1%). At baseline, **93.4% of patients were malnourished** according to GLIM criteria, and **19.4% had sarcopenia**.

After three months of intervention, significant improvements were observed:

A) Changes in the Diagnosis of Malnutrition and Sarcopenia:

Malnutrition prevalence dropped from 93.4% to 78.9% ($p<0.01$) and severe malnutrition from 60.7% to 40.3% ($p<0.01$). Patients aged ≥ 60 years showed reductions in malnutrition and severe malnutrition too.

Sarcopenia prevalence decreased from 19.4% to 15.5% ($p=0.04$), with improvements only in patients aged ≥ 60 years.



B) Evolution of Morphofunctional Assessment Variables:

A significant improvement was observed in the % body weight loss from -6.75% to 0.5% ($p<0.01$). Appendicular skeletal muscle index (ASMI) increased from 5.69 to 6.34 kg/m² ($p<0.01$). Improvements were noted in Rectus Femoris Muscle Area (RFMA) ($p=0.03$) and gray level non-uniformity ($p=0.03$). Patients aged ≥ 60 years showed significant increases in RFMA, Rectus Femoris Muscle Thickness (RFMT), gray level heterogeneity, pennation angle, subcutaneous fat, and handgrip strength.

C) GI Tolerance and Compliance Rate:

The cHPHC-ONS had good GI tolerance, with only two patients (3.1%) experiencing diarrhea.

Compliance was over 75% in 78.5% of patients, 50-75% in 7.7%, 25-50% in 6.2%, and less than 25% in 6.2%.

This study demonstrates that a novel concentrated high-protein (32g/200mL), high-calorie (≥2.1 kcal/mL) oral nutritional supplement, combining fast-acting (60% whey protein) and slow-acting (40% casein) proteins, significantly reduces the prevalence of malnutrition, severe malnutrition, and sarcopenia along with notable improvements in muscle mass, quality, and overall muscle strength, all achieved with a high compliance rate in patients suffering from DRM and sarcopenia.

** cHPHC-ONS used in this study was Meritene® Clinical Extra Protein (Nestlé Health Science, Spain). This nearly identical formula can be found in other countries under different brand names: Resource® Ultra+, Resource® Ultra, Clinutren® Ultra, or Nutren® Ultra. These products offer a nearly identical formula to Meritene® Clinical, containing the same amount and type of protein (32g; 60% whey: 40% casein), with minimal differences in micronutrient content. Meritene® contains only 0.15kcal/ml less than the other mentioned products and slightly less carbohydrates (0.02g/ml) and fats (0.0075g/ml).