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Società Italiana di Nutrizione Artificiale e Metabolismo

INCREASE MALNUTRITION AWARENESS:
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# PROSPECTIVE COHORT STUDY ON THE EFFECTIVENESS OF THE CROHN'S DISEASE EXCLUSION DIET + PARTIAL ENTERAL NUTRITION IN INDUCING AND MAINTAINING REMISSION IN ADULT PATIENTS WITH CROHN'S DISEASE

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## Rationale

In several studies on patients up to 17 years of age with Crohn's disease (CD) exclusive enteral nutrition (EEN) has achieved results comparable to those obtained with steroid therapy in inducing clinical remission. In recent years, the effectiveness of a specific elimination diet for CD, the Crohn's Disease Exclusion Diet (CDED) + Partial Enteral Nutrition (PEN), has been demonstrated, designed with the aim of eliminating components of the diet that could cause inflammation intestinal, with possible subsequent exacerbations of the disease, and to modify the microbiota in a favorable direction. The CDED + PEN approach, by removing the limitation of EEN compliance for the adult patient, could be an effective therapy in inducing remission even in patients aged ≥18 years.

## Methods

Enrolled patients will be treated with CDED + PEN diet using Modulen® IBD according to the Modulife scheme: phase 1 for 6 weeks, phase 2 from week 6 to 12, phase 3 maintenance for one year starting from week 13. The goal is to recruit 30 patients and follow them for one year. Since no other studies have evaluated the long-term efficacy of CDED (for 1 year). The following biochemical analyzes will be performed: PCR, faecal calprotectin, serum ESR, total protein, albumin. At T0 and T2 the following will also be measured: IL-2, IL-4, IL-6, IL-8, IL-10, GMCSF, INF-γ, TNF-α, serum zonulin. The Modulife regimen will be offered to all patients with active CD who need a therapeutic escalation.

## Results

PRIMARY ENDPOINT: Ability of CDED+PEN to induce clinical response (HBI reduction greater than 3 points) and remission (HBI<5) at the end of the induction phase (week 12), sparing patients from steroid therapy or escalation to immunosuppressant or biologics.
SECONDARY ENDPOINT: maintenance of remission up to 1 year without pharmacological escalation; evaluation of the reduction of CRP, ESR, faecal calprotectin; improvement of nutritional status evaluated both from a laboratory point of view that from anthropometric data and body composition, the latter evaluated by means of bioimpedance analysis (BIA); through the validated SF12 questionnaire the subjective improvement in quality of life.

## Conclusion

We expect the CDED+PEN therapeutic approach to induce remission in patients with active CD disease. Furthermore, unlike steroids, CDED + PEN could also maintain remission up to 1 year of follow-up to avoid therapy escalation.

## References

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- *The Crohn's disease exclusion diet for induction and maintenance of remission in adults with mild-to-moderate Crohn's disease (CDED-AD): an open-label, pilot, randomized trial - Henit Yanai*, Arie Levine*et al; Lancet Gastroenterol Hepatol (2021)*
- *Crohn's disease exclusion diet in children with Crohn's disease: a case series - Luca Scarallo, Elena Banci, Valentina Pierattini & Paolo Lionetti; Current Medical Research (2021)*
- *Dietary therapy with the Crohn's Disease exclusion diet induces sustained clinical and endoscopic remission in adults with Mild to Moderate Crohn's Disease: Results from the CDED-AD trial H. Yanai*1,2.*
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