Double-blind randomized controlled study of linoleic acid supplementation for 1 year in patients with cystic fibrosis.

–Influence on clinical status and metabolism.

-NETwork study of LA supplementation in CF patients (NETLACF)

The study is registered at ClinTrial.gov ID #NCT04531410

Funding: European Society of Pediatric Gastroenterology and Nutrition; Swedish CF Association; Heart-Lung Foundation; Erica Lederhausen´s Foundation.

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9. *Statistics*

All data will be collected in identical Excel files and analysed in one center at end study.

The main analysis will be carried out on the intention-to-treat population defined as all randomized patients. We will also conduct a secondary analysis on the per-protocol population excluding patients not receiving the allocated treatment for more than 2 months.

Between-treatment differences in the primary outcome across time points will be evaluated by fitting random intercept linear mixed-effects models. Mixed effects model can account for intra-correlated repeated measures on the same subjects and accommodate missing data due to dropouts. The models will include the z-score of BMI as response variable, treatment, time and time x treatment interaction as independent variables. The model coefficients for the time x treatment interaction will be considered an estimate of the treatment effect on changes in the study outcome. Time will be included in the model as categorical variable with the following categories: baseline (pre-treatment), +6 months and +12 months from treatment allocation.

Seondary and explanatory outcomes will be compared across treatment groups using the paired t-test for normally distributed variables, otherwise the non-parametric Wilcoxon signed-rank test for dependent samples will be used.

A stratified analysis by sex will be performed.