primary studies - published RCT

Probiotics in cystic fibrosis patients: a double blind crossover placebo controlled study: pilot study from the ESPGHAN Working Group on Pancreas/CF

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Study design (if review, criteria of inclusion for studies)

Doubleâ€•blind multicenter crossâ€•over study (2 x 4 m)

Participants

31 CF patients entered the study of which 25 finished it. At start patients aged 9.3yrs (6.9â€•12.2), had a median BMI zâ€•score of â€•0.5 (â€•1.5â€•0.08), height zâ€•score of â€•0.4 (â€•1.1â€•0.05) and FEV1% of 100% (87.2â€•106.6). Median FCP at start was 61 mug/g (17â€•108) and gut permeability 0.079 (0.051â€•0.122).

Interventions

Probiotics

Outcome measures

Abdominal pain, nutritional status, pulmonary function, pulmonary exacerbation, fecal calprotectin (FCP) and lactulose/mannitol gut permeability test. Patients kept a diary with daily scoring of abdominal pain, stool frequency and consistency as well as treatment changes.

Main results

No significant changes were observed in the clinical parameters (BMI, FEV1%, abdominal pain, exacerbations). Despite being frequently abnormal (17/28 (61%) >50 mg/kg), FCP did not change significantly with probiotics. The proportion of patients with normal permeability was 8% during placebo and 32% during probiotic treatment (p = 0.031). FCP correlated to BMI zâ€•score (p = 0.043) and gut permeability to abdominal pain (p = 0.015). The microbiome revealed a high predominance of Actinobacteria and Proteobacteriae. Probiotic supplementation did not result in a shift at the phylum nor at phylogenetic level.

Authors' conclusions

Normalization of gut permeability was observed in 13% of patients during probiotic treatment. However, none of the previously described effects could be confirmed.

https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01623615/full

See also

Clinical nutrition ESPEN

Keywords

Probiotics; Immunoregulatory; pharmacological_intervention;