ongoing trials - trial from other registries

Pseudomonas aeruginosa eradication in patients with cystic fibrosis: a randomised multicentre study comparing classic treatment protocols with classic treatment together with antibiotic treatment of upper airways

Code: CN-XXXXX008 **Year:** 2019 **Date:** 45938 **Author:** Taccetti G

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

Randomization: Randomized, Blinding: Double blinded, Placebo: Used, Assignment: Parallel, Purpose: Treatment, Randomization description: Randomization Method: Block Randomization (Randomization Block Method) In this method, participants are divided into blocks of four, and the order of assignment to the probiotic or placebo groups is determined randomly. This method ensures that the number of participants in each group is equal at the end of each block, maintaining balance between the groups. Unit of Randomization: Individual Randomization Each participant is independently and randomly assigned to one of the two groups (probiotic or placebo). Stratification: on similar age groups to maintain age homogeneity between the groups. Randomization Tool: Randomization List Generation of Random Sequence: The order of group assignments within each block of four participants was determined randomly. Allocation Concealment: The study was conducted as a double-blind trial (Double-blin

Participants

Definitive diagnosis of cystic fibrosis (CF) confirmed by a specialist physician, with medical documentation including pancreatic insufficiency and fecal elastase less than 200 µg/g Age between 6 and 13 years Stable clinical condition: The child must be in a stable clinical state and must not have had an acute infection or hospitalization in the 4 weeks prior to the start of the study

Interventions

Intervention group: daily, for a period of two months, one sachet of a probiotic containing Lactobacillus reuteri at a dose of 1X108 CFU/day. Intervention 2: Control group: daily for two months, a placebo sachet containing maltodextrin and 1% magnesium stearate, and free of any live bacteria

Outcome measures

Change in total quality of life score after two months of probiotic (Lactobacillus reuteri) consumption compared with placebo, based on the standardized Cystic Fibrosis Quality of Life Questionnaire (CF-QoL). Timepoint: two months after consumption.

See also

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Keywords

Adolescent; Child; Lactobacillus; Probiotics; Supplementation; Oral; Immunoregulatory; pharmacological_intervention; Adult;