

primary studies - published RCT

Efficacy and Safety of a New Formulation of Pancrelipase (Ultrase MT20) in the Treatment of Malabsorption in Exocrine Pancreatic Insufficiency in Cystic Fibrosis.

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Year: 2010 **Date:** 2013

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

randomized double-blind placebo-controlled study

Participants

61 CF patients with mild-to-moderate lung disease at Regional Center for CF of the Department of Pediatrics of Sapienza - University of Rome. All patients were not hospital inpatients at the time of the enrolment. Inclusion criteria: 1) Forced expiratory volume in the 1 second (FEV1) > 70% predicted, 2) no inhaled or systemic steroids 2) no anti-inflammatory drugs, antileukotrienes and mast cell membrane stabilizers 3) no serious organ involvement. Exclusion criteria: 1) a history of pulmonary exacerbation or upper respiratory infection in the previous 2 months, 2) changes in medications in the past 2 months, 3) an history of hemoptysis in the past 2 months, 4) colonization with *B. cepacia* or mycobacteria.

Interventions

LR (30 patients) in 5 drops per day (10 colony-forming units) or Placebo (31 patients) for 6 months.

Outcome measures

Number of episodes of pulmonary exacerbations and of hospital admissions for pulmonary exacerbations, number of gastrointestinal and upper respiratory tract infections. Forced expiratory volume in the 1 second (FEV1), fecal calprotectin and cytokine profile in induced sputum and plasma were assessed at baseline and at the end of the trial.

Main results

Pulmonary exacerbations were significantly reduced in the LR group compared to the placebo group (p

Authors' conclusions

LR reduces pulmonary exacerbations and upper respiratory tract infections in CF patients with mild-to-moderate lung disease. LR administration might have a beneficial effect on the disease course of CF.

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See also

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Keywords

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