Cochrane Database of Systematic Reviews - - Cochrane Review

Probiotics for people with cystic fibrosis

Code: CD012949 **Year:** 2020 **Date:** 2018 - updated: 29 January 2020 **Author:** Coffey M

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

RCTs and quasi-RCTs which assess efficacies of probiotics in children and adults with CF. Cross-over RCTs will be included; however, only results from the first phase of each trial will be analysed if no 'washout' period is included in the trial design.

List of included studies (12)

Bruzzese 2007; Bruzzese 2014; Bruzzese 2018; de Freitas 2018; del Campo 2009; del Campo 2014; Di Benedetto 1998; Di Nardo 2014; Fallahi 2013; NCT01201434; Van Biervliet 2018

Participants

CF patients. No restrictions for included participants will be placed on age, gender, genotype, pancreatic exocrine sufficiency status, disease severity, co-morbidities, antibiotic use or CFTR modulator therapy

Interventions

Any oral probiotic formulation (any strain(s), dose or formulation, with or without a prebiotic) compared to any other probiotic formulation, placebo or no treatment control.

Outcome measures

Primary outcomes: Pulmonary exacerbation (consensus criteria e.g. Fuch's criteria); inflammatory biomarkers (mean change from baseline and post-treatment absolute mean); adverse events.

Main results

Authors identified 17 trials and included 12 RCTs (11 completed and one trial protocol â€• this trial was terminated early) (464 participants). Eight trials included only children, whilst four trials included both children and adults. Trial duration ranged from one to 12 months. Nine trials compared a probiotic (seven single strain and three multistrain preparations) with a placebo preparation, two trials compared a synbiotic (multistrain) with a placebo preparation and one trial compared two probiotic preparations. Overall we judged the risk of bias in the 12 trials to be low. Three trials had a high risk of performance bias, two trials a high risk of attrition bias and six trials a high risk of reporting bias. Only two trials were judged to have low or unclear risk of bias for all domains. Four trials were sponsored by grants only, two trials by industry only, two trials by both grants and industry and three trials had an unknown funding source. Combined data from four trials (225 participants) suggested probiotics may reduce the number of pulmonary exacerbations during a four to 12 month timeâ€•frame, mean difference (MD) â€•0.32 episodes per participant (95% confidence interval (CI) â€•0.68 to 0.03; P = 0.07) (lowâ€•certainty evidence); however, the 95% CI includes the possibility of both an increased and a reduced number of exacerbations. Additionally, two trials (127 participants) found no evidence of an effect on the duration of antibiotic therapy during the same time period. Combined data from four trials (177 participants) demonstrated probiotics may reduce faecal calprotectin, MD â€•47.4 Âµg/g (95% CI â€•93.28 to â€•1.54; P = 0.04) (lowâ€•certainty evidence), but the results for other biomarkers mainly did not show any difference between probiotics and placebo. Two trials (91 participants) found no evidence of effect on height, weight or body mass index (lowâ€•certainty evidence). Combined data from five trials (284 participants) suggested there was no difference in lung function (forced expiratory volume at one second (FEV1) % predicted) during a threeâ€• to 12â€•month time frame, MD 1.36% (95% CI â€•1.20 to 3.91; P = 0.30) (lowâ€•certainty evidence). Combined data from two trials (115 participants) suggested there was no difference in hospitalisation rates during a threeâ€• to 12â€•month time frame, MD â€•0.44 admissions per participant (95% CI â€•1.41 to 0.54; P = 0.38) (lowâ€•certainty evidence). One trial (37 participants) reported healthâ€•related quality of life and while the parent report favoured probiotics, SMD 0.87 (95% CI 0.19 to 1.55) the child selfâ€•report did not identify any effect, SMD 0.59 (95% CI â€•0.07 to 1.26) (lowâ€•certainty evidence). There were limited results for gastrointestinal symptoms and intestinal microbial profile which were not analysable. Only four trials and one trial protocol (298 participants) reported adverse events as a priori hypotheses. No trials reported any deaths. One terminated trial (12 participants and available as a protocol only) reported a severe allergic reaction (severe urticaria) for one participant in the probiotic group. Two trials reported a single adverse event each (vomiting in one child and diarrhoea in one child). The estimated number needed to harm for any adverse reaction (serious or not) is 52 people (lowâ€•certainty evidence).

Authors' conclusions

s. Given the variability of probiotic composition and dosage, further adequatelyâ€•powered multicentre RCTs of at least 12 months

duration are required to best assess the efficacy and safety of probiotics for children and adults with CF.

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See also

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Keywords

Probiotics; Immunoregulatory; pharmacological_intervention;