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Probiotics in the prevention of antibiotic-associated and *C. difficile* diarrhoea in elderly in-patients: PLACIDE - A randomised, controlled trial

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Antibiotic-associated diarrhoea (AAD), including *Clostridium difficile* diarrhoea (CDD), causes significant morbidity and mortality in older hospitalised people. Although underlying disease mechanisms are poorly understood, meta-analyses have provided some support for probiotics in the prevention of AAD.

In a multicenter, randomised, double blind, placebo-controlled, parallel arm, pragmatic trial, we allocated in-patients aged ≥65 years and exposed to one or more oral or parenteral antibiotics to receive either a multi-strain preparation of lactobacilli and *bifidobacteria* (total of 6 x 10^{10} organisms/day) for 21 days or an identical placebo. The main outcomes were AAD occurring within 8 weeks and CDD within 12 weeks of recruitment. The trial is registered: ISRCTN70017204.

In the probiotic and placebo arms respectively, AAD (including CDD) occurred in 159/1470 (10.8%) and 153/1471 (10.4%) participants (OR 1.04; 95% CI 0.83-1.32; P=0.72) and CDD occurred in 12/1470 (0.8%) and 17/1471 (1.2%) participants (OR 0.70; 95% CI 0.34-1.48; P=0.35). Secondary outcomes such as duration and severity of diarrhoea, gastrointestinal symptoms, serious adverse events, duration of hospital stay and quality of life were also similar in the two arms. Accounting for compliance with the trial interventions and potential risk factors for AAD did not materially change the results. Updated meta-analyses including our findings showed marked statistical heterogeneity in the pooled results.

Administration of a multi-strain, high dose probiotic was not effective in preventing AAD in older in-patients. Further studies should be guided by a better understanding of the pathophysiology of AAD and need to account for the falling frequency of CDD in some settings.

Biography

Steve Allen completed his MD from Birmingham University Medical School, UK. He is a Paediatric Gastroenterologist based in Swansea, UK and is also the International Officer and David Baum International Fellow for the Royal College of Paediatrics and Child Health, UK. He leads a Cochrane review of probiotics in the treatment of acute diarrhoea and has undertaken research in probiotics in the prevention of atopy in infants and also studies in malaria and haemoglobinopathies. He has over 60 papers in reputed journals.

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