Submission Id: 4765

Title

Efficacy and Safety of BB-12 Supplemented Strawberry Yogurt For Healthy Children on Antibiotics (PLAY ON)

Priority 1 (Research Category)

Acute respiratory infections

Presenters

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Abstract

Context: Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host. One of the most common indications for probiotic treatment is the prevention of antibiotic-associated diarrhea (AAD). Unfortunately, many probiotic products used for AAD are not supported by rigorous independent research, and often results in non-evidence-based usage. The overarching objective is to move research forward for the most well-studied Bifidobacterium strain. Objectives: The primary aim is to test the efficacy of high dose, BB-12-supplemented yogurt in preventing AAD, compared to yogurt without BB-12, in children receiving antibiotics. Other aims are to further assess the safety of yogurt supplemented with BB-12, and to carry out longitudinal community structure and gene expression analysis of fecal microbiota to evaluate the impact of high dose BB-12 in a pediatric population receiving antibiotics. The microbiota includes hundreds of species, and its disruption is hypothesized to be an important factor in the development of AAD. AIM 1: To test the efficacy of high dose, BB-12-supplemented yogurt in preventing AAD, compared to yogurt without BB-12, in children receiving antibiotics. Hypothesis: Children receiving antibiotics who receive the yogurt with BB-12 will demonstrate less diarrhea than those receiving a control yogurt without BB-12. This is a Phase II trial that requires additional safety evaluation of high dose BB-12. Hypotheses 3: (i) Administration of antibiotics will alter the composition and gene expression profile of the gut microbiota in pediatric patients, and (ii) concomitant ingestion of BB-12 in yogurt will mitigate the antibiotic-induced disturbance in the gut microbiota, as identified using 16S rRNA and metatranscriptomic profiling. Study Design and Analysis: We will finish in the June 2023 a Phase II, randomized, double-blinded controlled trial with allocation concealment. Setting: Capital Areal Primary Care Practice Based Research Network. Population Studied: 270 patients, ages 3-12 years, clinically diagnosed with a respiratory infection requiring 7-10 days of antibiotics. Interventions: The two arms are, BB-12-supplemented yogurt and non-supplemented control yogurt, in a 1:1 randomized allocation. Participants of all ages will be asked to consume the same dose, 100 ml, of product per day. The 100 ml serving of probiotic yogurt will deliver ≥1010 CFU of BB-12. The BB-12 probiotic was not be added