NAPCRG 52nd Annual Meeting — Abstracts of Completed Research 2024.

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Title

The PLAY ON Study, Probiotics: Live and Active Yogurt Cultures for Healthy Children on Antibiotics

Priority 1 (Research Category)

Clinical trial

Presenters

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Abstract

Context: Antibiotic-associated diarrhea (AAD) is one of the most common side effects of antibiotics. Children and adults are often placed on antibiotics and the rate of diarrhea associated with antibiotic usage is 20-35%. Probiotics have the potential to reduce the rate of AAD. Bifidobacterium species, particularly B. lactis BB-12, the principal focus of this study, can be found in the gastrointestinal tract (GIT) as both autochthonous and allochthonous residents.

Objective: The primary objective was to test the efficacy of high dose BB-12 supplemented yogurt in preventing AAD, compared to yogurt without BB-12, in children receiving antibiotics. The secondary objectives were to 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.

Study Design: This was a randomized, blinded with true allocation concealment Phase 2 study to test the efficacy of BB-12 yogurt in preventing AAD, compared to yogurt without BB-12, in children receiving antibiotics for a respiratory infection. Children prescribed a 7-10- day penicillin or cephalosporin class antibiotic for a respiratory infection, who meet all the inclusion and exclusion criteria were enrolled.Setting & Population Studied: Participants were recruited through Capital Area Primary Care Research Network (CAPRICORN), a practice-based research network (PBRN). There was no exclusion based on race, gender, or insurance status.

Results: Two hundred and fifty-five participants (Active=125, Control=130) were recruited and randomized in this study. The average age was 6.5 years, 52% were female, 45% were identified as

Hispanic, and over 90% had insurance. There was no significant difference in the occurrence of diarrhea between the BB-12 and control groups as both groups had a 2% rate of diarrhea. There was also no significant difference in rates of loose stools or AEs. Conclusion: We found much lower rates of diarrhea than reported in the literature. We are currently analyzing the 16S data and alpha diversity results for metagenomics.