The Effect Cranberry-Based Products on the Female Microbiome

NCT07109713

Status	RECRUITING
Phase	Not Applicable
Sponsor	Ocean Spray Cranberries, Inc.
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (5)

- Pre-menopausal female,
- years of age (inclusive) at visit 1.
- History of regular menstrual cycles (21-35 d per cycle or at the investigator's discretion) for at least 3 months prior to visit 1. Participants that are using contraceptives (IUD, patch, or pills) must be on a stable dose, defined as no change in medication regimen, within 90 days of visit 1 (or within 6 months of visit 1 for copper IUD users) and no plans to change hormonal contraceptive use during the study.
- BMI e18.5 to \<30.0 kg/m2 at visit 1.
- Willing to adhere to all study procedures, including lifestyle considerations (see section 6.2), and sign forms providing informed consent to participate in the study and authorization to release relevant protected health information to the Clinical Investigator.

Exclusion (26)

- Women's health related criteria
- •Female who is pregnant, planning to be pregnant during the study period, lactating, or is of childbearing potential and is unwilling to commit to the use of a medically approved form of contraception throughout the study period.
- General health related criteria
- Participant has a history or presence of any gastrointestinal condition that could potentially interfere with absorption of the study product (e.g., inflammatory bowel syndrome, celiac disease, history of gastric bypass surgery).
- History or presence of clinically important cardiac, renal, hepatic, endocrine (including diabetes mellitus), pulmonary, gastrointestinal, biliary, pancreatic, or neurological disorders that may affect the participant's ability to adhere to the study protocol and/or affect study outcomes, in the judgment of the Investigator.

... and 21 more (see full listing online)

Locations (1 total)

Biofortis, Chicago, Illinois, United States