

Colon-delivered Riboflavin and Gut Microbiota Composition

NCT07093463

Status	RECRUITING
Phase	Not Applicable
Sponsor	dsm-firmenich Switzerland AG
Enrollment	90 participants

Key Eligibility Criteria

Inclusion (11)

- Individuals providing written informed consent for participation in the study and data processing
 - Female and males between 50 and 70 years of age
 - For females only: Menopausal as marked by at least 1 year since the last menstrual bleeding
 - Individuals with a BMI between 18.5 - 29.9 Kg/m²
 - Individuals with stable body weight (d5% change) over the past 3 months prior to V1
- ... and 6 more (see full listing online)

Exclusion (22)

- Individuals who are hypersensitive/intolerant to any of the components of the Investigational product or the standardised diet addition (inulin)
 - Individuals who have taken systemic antibiotics within the previous 3 months prior to Baseline (V2) or are expected to be taking any during the study
 - Individuals who consumed microbiome modulating dietary supplements, prebiotic, probiotic, or fibre-rich supplements within 4 weeks prior to the baseline (V2)
 - Individuals who are currently regularly using systemic steroids, proton pump inhibitors, H2 blocker, antacids (however, sporadic use during the study if needed is allowed, but not within 8 hours before each visit), metformin if started less than 6 months prior to V1, or immunosuppressant medication.
 - Individuals who have a history of drug abuse in the previous 5 years and/or alcohol abuse at the time of enrolment (>11 units/week for women; >17 units/week for men; unit: approx. 125 mL of wine or similar / approx. 30 mL of spirits)
- ... and 17 more (see full listing online)

Locations (1 total)

analyze & realize GmbH, Berlin, State of Berlin, Germany