

Tolerance Profile of Soluble Fibers in Individuals With Self-perceived GI Sensitivity to Fibers (Tarine)

NCT06877013

Status	RECRUITING
Phase	Not Applicable
Sponsor	Danone Global Research & Innovation Center
Enrollment	173 participants

Key Eligibility Criteria

Inclusion (11)

- years of age inclusive, and Body Mass Index (BMI) 18.5-29.9 kg/m² inclusive; who according to the Rome IV fulfil criteria for self-perceived sensitivity to oligosaccharide FODMAP A and B including participants diagnosed with IBS, FBF, or FBD-U.
- years of age inclusive, and BMI 18.5-29.9 kg/m² inclusive; who fulfil criteria for self-perceived sensitivity to oligosaccharide FODMAP A and B, not diagnosed with IBS, FB or FBD-U as per Rome IV Criteria but reporting abdominal pain at least once a week AND/OR bloating/distention at least once a week as per ROME IV diagnostic questionnaire.
- Individuals who fully understand the objectives of the study, who are willing to provide consent and agree to follow the protocol of the study.
- Participant is covered by French health insurance.
- Participant agrees to be registered in the national database of participants participating in clinical research.

... and 6 more (see full listing online)

Exclusion (28)

- Individuals who score below 75 or who score 300 or above on the Irritable Bowel Syndrome Severity Scoring System (IBS-SSS) if diagnosed with IBS using the Rome IV criteria.
- Individuals that are diagnosed with any other chronic gastrointestinal or metabolic disease or condition including inflammatory bowel disease, coeliac disease, fistulas or physiological/mechanical gastrointestinal obstruction, diverticulitis, gastric bezoar, radiation enteritis, suspected or known strictures.
- Change of dietary habits within the 4 weeks preceding V1 (e.g., start of a diet rich in fibers) or planned change (e.g., start of a new diet during study participation).
- Individuals with specific and extreme diets (e.g.: strict low-FODMAP, gluten free, high fiber diet, etc.).
- Individuals who anticipate changes to consumption of naturally probiotic/prebiotic containing foods e.g., yogurt with live cultures etc., in the next 2 months.

... and 23 more (see full listing online)

Locations (1 total)

CEN experimental, Dijon, France

<https://clinicaltrials.gov/study/NCT06877013>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).