Safety, and Efficacy Study of ShigETEC, a Live, Attenuated, Oral Combination Vaccine to Prevent Shigella and ETEC Disease Delivered to Healthy Adults Ages 18 to 50 Years Old

NCT07049159

Status	RECRUITING
Phase	Phase 2
Sponsor	Eveliqure Biotechnologies GmbH
Enrollment	72 participants

Plain Language Summary

This study tests a new oral vaccine called ShigETEC designed to protect against two common causes of severe diarrhea: Shigella bacteria and a strain of E. coli called ETEC. This type of diarrhea can be dangerous, especially in travelers and people in areas with limited clean water.

You may be eligible if:
- You are a healthy adult between 18 and 50 years old
- You are not pregnant or nursing
- You have a BMI between 19 and 40
- You are willing to stay at an inpatient unit for observation during part of the study
- You agree to use effective birth control during the study

You may NOT be eligible if:
- You have a history of serious gastrointestinal disease (e.g., inflammatory bowel disease, liver disease)
- You have taken antibiotics, probiotics, or antacids within 7 days before the vaccine dose
- You have a weakened immune system
- You work as a food handler or in direct patient/childcare
- You have an immunocompromised person or a child under 2 in your household
- You have had a confirmed Shigella or ETEC infection in the past 5 years
- You have known allergies to study drug components (including soy or PEG)

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (9)

- Generally healthy non-pregnant, non-nursing adults aged 18 to 50 years.
- Who are determined by medical history, physical examination, laboratory testing, and clinical judgment to be eligible for this study.
- Who provide written informed consent after the nature of the study had been explained.
- Who are available for the duration of the trial (from enrollment to study completion).
- Who are able to understand and are willing to comply with all study requirements, and willing to follow the instructions of the study staff and complete a comprehension test.

... and 4 more (see full listing online)

Exclusion (37)

- Participants who are perceived to be unavailable or difficult to contact for evaluation or study visits during the study period.

• Presence of a significant medical or psychiatric condition which in the opinion of the Investigator precludes participation in the study.

• Clinically significant abnormalities in screening hematology or serum chemistry, defined as \> grade 1 abnormality of serum potassium, alanine aminotransferase (ALT) or creatinine, hemoglobin, white blood cell count (WBC), or neutrophil count.

• Who have received any blood products, including immunoglobulin, in the period from 6 months prior to vaccination or are anticipated to receive such products through to the conclusion of the study and have not donated blood within 30 days and agree not to donate blood until 1 year after challenge.

• Who are receiving systemic antibiotics, completed antibiotic therapy, or receiving probiotics, prebiotics or synbiotics in previous 7 days before vaccination, or proton pump inhibitors, H2 blockers, or antacids within 48 hours of dosing with vaccine.

... and 32 more (see full listing online)

Locations (1 total)

Center for Immunization Research, Baltimore, Maryland, United States