Extended Dosing Intervals Trial for Oral Cholera Vaccine, Kenya

NCT07487077

Status	RECRUITING
Phase	Phase 4
Sponsor	Albert B. Sabin Vaccine Institute
Enrollment	1,071 participants

Key Eligibility Criteria

Inclusion (6)

- Residents of Mukuru, Nairobi, Kenya
- Individuals aged 1 year and above
- Voluntary written informed consent for study participation provided by an individual or his/her legally acceptable representative. Children aged 13 years and above will also provide assent, with parental permission required for all children.
- Ability to comply with study requirements and attend follow-up visits during the study period.
- Participants must be in good health, as determined by medical history, physical examination, and the clinical judgment of the investigators. Clinical judgment will consider factors such as the absence of acute illness or, uncontrolled or severe chronic conditions that may affect participation in the study.

... and 1 more (see full listing online)

Exclusion (11)

- Known history of hypersensitivity reactions to other vaccines.
- Pregnant women, due to differences in immune response. A pregnancy test will be administered to all female participants who have reached menarche and are under 50 years.
- Reported diarrhea or abdominal pain lasting 2 weeks or longer within 6 months prior to study initiation; to avoid confounding the vaccine's effects with pre-existing conditions.
- Received a cholera vaccine in the last 24 months: Ensures that the study assesses the vaccine in question without interference from prior vaccinations.
- History of cholera disease in the last 24 months: Recent history of cholera infection can interfere with the measurement of vaccine response.

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

Locations (1 total)

KEMRI, Nairobi, Kenya