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A Study to Evaluate Safety and Immunogenicity of tOPV in 1 to 5 Years and at 6 Weeks of Age (T2-ABMG)

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified August 2015 by Fidec Corporation

Sponsor:
Fidec Corporation

Collaborator:
Bill and Melinda Gates Foundation

Information provided by (Responsible Party):
Fidec Corporation

ClinicalTrials.gov Identifier:
NCT02580201

First received: August 21, 2015
Last updated: October 19, 2015
Last verified: August 2015
History of Changes

Purpose

The purpose of this study is to assess the safety (serious adverse events [SAEs]), and severe adverse events [AEs] (grade 3 according to CTCAE 4.03) after one dose of SABIN tOPV in 1-5 year-old children and three doses of SABIN tOPV in 6 week-old infants, and immunogenicity (seroprotection rates for all 3 serotypes) 28 days after three doses of SABIN tOPV in vaccine-naïve infants.

Condition	Intervention	Phase
Poliomyelitis	Biological: Oral Polio Vaccine	Phase 4

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Prevention

Official Title: A Phase 4 Study to Evaluate the Safety and Immunogenicity of Trivalent Oral Polio Vaccine in Healthy Polio Vaccinated Children 1 to 5 Years of Age and in Healthy Unvaccinated Infants at 6 Weeks of Age in the Dominican Republic

Resource links provided by NLM:

MedlinePlus related topics: Polio and Post-Polio Syndrome

Genetic and Rare Diseases Information Center resources: Children's Interstitial Lung Disease Myelitis Poliomyelitis

U.S. FDA Resources

Further study details as provided by Fidec Corporation:

Primary Outcome Measures:

- To evaluate the Safety 28 days after three doses of SABIN tOPV in vaccine-naïve infants in Dominican Republic. [Time Frame: 6 months] [Designated as safety issue: No]

  Incidence of SAEs and severe AEs grade 3 considered consistent with a causal association to study vaccine throughout the study period in children (Group 1) and infants (Group 2). Immunogenicity: seroprotection rate of type-specific polio neutralizing antibodies at Day 84, 28 days after the third dose of SABIN tOPV in infants (Group 2). (Seroprotection is defined as type-specific antibody titers ≥1:8 and seroprotection rate as the percentage of seroprotected subjects per group.)

Estimated Enrollment: 154
Study Start Date: November 2015
Estimated Study Completion Date: July 2016
Estimated Primary Completion Date: March 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Oral Polio Vaccine Opvero™ (oral) is a trivalent, live attenuated poliomyelitis virus	Biological: Oral Polio Vaccine Opvero™ (oral) is a trivalent, live attenuated poliomyelitis virus

vaccine containing at least 6.0 log 50% cell culture infective dose (CCID50) of LS c2ab strain of live attenuated polio virus type 1, 5.0 log CCID50 of P712, Ch, 2ab strain of live attenuated polio virus type 2, 5.8 log CCID50 Leon I2alb strain of polio virus type 3. Excipients: human albumin, HEPES buffer solution, magnesium chloride solution (containing polysorbate 80 and phenol red), hydrochloric acid or sodium hydroxide for pH adjustment. The vaccine is presented as a suspension for oral administration. One dose of vaccine (0.1 ml) is contained in two drops which are delivered from the dropper supplied with the multidose container.	vaccine containing at least 6.0 log 50% cell culture infective dose (CCID50) of LS c2ab strain of live attenuated polio virus type 1, 5.0 log CCID50 of P712, Ch, 2ab strain of live attenuated polio virus type 2, 5.8 log CCID50 Leon I2alb strain of polio virus type 3. Excipients: human albumin, HEPES buffer solution, magnesium chloride solution (containing polysorbate 80 and phenol red), hydrochloric acid or sodium hydroxide for pH adjustment. The vaccine is presented as a suspension for oral administration. One dose of vaccine (0.1 ml) is contained in two drops which are delivered from the dropper supplied with the multidose container.

Detailed Description:
This will be a single center, open study in children (aged 1 to 5 years) and vaccine-naïve infants, as follows: 50 OPV-vaccinated children aged 1 to 5 years to receive 1 dose of tOPV (Group 1); 104 vaccine-naïve infants to receive 3 doses of tOPV administered 28 days apart (Group 2)

Eligibility

Ages Eligible for Study:	5 Weeks to 5 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

1. Age: Group 1- Children aged 1-5 years, previously vaccinated with ≥ 3 doses of OPV. Group 2- Infants aged 6 weeks (-7 to +14 days) with no previous polio vaccinations.
2. Healthy without obvious medical conditions that preclude the subject to be in the study as established by the medical history and physical examination.
3. Written informed consent obtained from 1 or 2 parents or legal guardians as per Dominican Republic regulations.

Exclusion Criteria:

1. Previous Vaccinations: Group 1: Previous vaccination against poliovirus outside of the national immunization schedule and any vaccine in the previous 4 weeks. Group 2: Any vaccination against poliovirus
2. Group 2: Infants with birth weight (BW) < 2,500 gm.
3. Any confirmed or suspected immunosuppressive or known immunodeficient condition including human immunodeficiency virus (HIV) infection.
4. Family history of congenital or hereditary immunodeficiency.
5. Major congenital defects or serious uncontrolled chronic illness (neurologic, pulmonary, gastrointestinal, hepatic, renal, or endocrine).
6. Known allergy to any component of the study vaccines or to any antibiotics.
7. Uncontrolled coagulopathy or blood disorder contraindicating intramuscular injections.
8. Administration of immunoglobulins and/or any blood products since birth or planned administration during the study period.
9. Acute severe febrile illness at day of vaccination deemed by the Investigator to be a contraindication for vaccination (the child can be included at a later time if within age window and all in/exclusion criteria are met).
10. Member of the subject's household (living in the same house or apartment unit) has received OPV in the last 3 months, or is scheduled to receive OPV during the study period.
11. Subject who, in the opinion of the Investigator, is unlikely to comply with the protocol or is inappropriate to be included in the study for the safety or the benefit-risk ratio of the subject.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02580201

Contacts

Contact: Ricardo W Ruttimann, MD 1 305 854 0075 rruttimann@fidec-online.org

Contact: Valeria Rotholc, LLD 1 305 854 0075 vrotholc@fidec-online.org

Sponsors and Collaborators

Fidec Corporation

Bill and Melinda Gates Foundation

Investigators

Principal Investigator: Luis Rivera, MD Hospital Maternidad Nuestra Señora de la Altagracia

More Information

No publications provided

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Other Study ID Numbers:	T2-ABMG
Study First Received:	August 21, 2015
Last Updated:	October 19, 2015
Health Authority:	Dominican Republic: Consejo Nacional de Bioetica en Salud

Additional relevant MeSH terms:

Poliomyelitis	Nervous System Diseases
Central Nervous System Diseases	Neuromuscular Diseases
Central Nervous System Infections	Picornaviridae Infections
Central Nervous System Viral Diseases	RNA Virus Infections
Enterovirus Infections	Spinal Cord Diseases
Myelitis	Virus Diseases

ClinicalTrials.gov processed this record on December 17, 2015