

Study to Learn About Safety, Tolerability, and Immune Response of a Catch-up Pneumococcal Vaccine in Children and Adolescents

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 15 months to 17 years old

Healthy Volunteers: This study is also accepting healthy volunteers

Inclusion Criteria:

Cohort 1 (Participants ≥ 15 Months to < 2 Years of Age) Healthy toddlers and children ≥ 15 months to < 2 years of age with documentation of prior receipt of PCV.

Cohort 2 (Participants ≥ 2 Years to < 5 Years of Age) Healthy toddlers and children ≥ 2 years to < 5 years of age with documentation of prior receipt of PCV if applicable.

Cohort 3 (Participants ≥ 5 Years to < 18 Years of Age) Healthy children ≥ 5 years to < 18 years of age with documentation of prior receipt of PCV (if applicable). A negative urine pregnancy test is required for individuals of childbearing potential (IOCBP). IOCBP or participants able to father must also agree to use a highly effective method of birth control.

Exclusion Criteria:

All Cohorts (Participants ≥ 15 Months to < 18 Years of Age)

Children with significant medical, psychiatric, or neurological conditions (eg, immunodeficiency or history of seizure); or a history of confirmed invasive pneumococcal infection in the past will be excluded from enrolment in the trial

Conditions & Interventions

Interventions:

BIOLOGICAL: PG4, BIOLOGICAL: 20-valent pneumococcal conjugate vaccine (20vPnC)

Conditions:

Pneumococcal Disease

More Information

Description:

The purpose of this study is to learn about the safety of a new pneumococcal vaccine and how the new pneumococcal vaccine helps to fight against germs that can cause pneumonia (lung infections), meningitis (brain infections), and otitis media (ear infections) in children when compared to the pneumococcal vaccine that is currently in use, 20vPnC (Pneumovax 20®). This study will test if the new pneumococcal vaccine is as safe as the one that is currently in use. It will also assess how the new vaccine works in comparison to the one that is currently in use. To measure how the new pneumococcal vaccine compares to the current one, blood samples will be used to measure the body's ability to create proteins to fight those germs. This new vaccine can possibly provide additional protection against germs that cause pneumococcal disease that are not included in the vaccines that are currently given to children. Pneumococcal disease includes a variety of infections caused by a specific germ, Streptococcus pneumoniae. This study is seeking participants who: * Are children aged 15 months to 18 years. * May or may not have received any doses of pneumococcal conjugate vaccine (PCV) in the past. The study will be conducted in the United States, Puerto Rico, and other countries. Participants will be assigned to 1 of 3 groups based on age: Group 1: 15 months to less than 2 years (about 300 participants) Group 2: 2 years to less than 5 years (about 300 participants) Group 3: 5 years to less than 18 years (about 600 participants) Within each group, participants will be assigned by chance in a 2:1 ratio to receive 1 vaccine injection (shot) with either PG4 (new vaccine) or 20vPnC, given in the arm or thigh. This means that for every 3 participants, about 2 will receive PG4 and about 1 will receive 20vPnC. Each participant will take part in the study for approximately 6 months. During this time, each participant will visit a clinic 2 times (visit 1 for vaccination and visit 2 to follow up) and will be contacted via telephone once (for a 6 month follow up). At the study clinic visits, participants will have their blood drawn and be asked if they have experienced any side effects. A side effect is an unintentional or unexpected reaction to a vaccine. During the 6-month follow-up contact, participants will be asked about any further side effects.

Contact(s): - VaccineResearch@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: PHASE3

IRB Number:

System ID: NCT07660198

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