A Study of BLB-201 RSV Vaccine in Infants and Children

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 months to 5 years old
Healthy Volunteers: This study is also accepting healthy volunteers
Inclusion criteria for sero+ children 18 to 59 months of age enrolled in Groups 1 and 2:

Healthy children at least 18 months but less than 60 months of age whose legally-acceptable representative (LAR) understands and signs the trial informed consent and agrees to vaccine administration following a detailed explanation of the trial.

Determined by medical history, targeted physical exam, and clinical judgement of the investigator to be in a good state of health. Screening laboratory values slightly outside lab normal ranges may be acceptable if the site investigator determines that they are not clinically significant. Permitted concomitant medications include nutritional supplements, medications for gastroesophageal reflux, eye drops, and topical medications, including topical steroids, topical antibiotics, and topical antifungal agents.

Sero+ for RSV as defined by serum RSV antibody titer assay

Participant is expected to be available for the duration of the trial.

The LAR confirms that the subject has received routine immunizations appropriate for age based on the current Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger.

Growing normally for age as demonstrated on a World Health Organization (WHO) growth chart, AND has a current height and weight above the 3rd percentile for age.

Inclusion criteria for sero+ or sero- infants and children 8 to 24 months of age enrolled in Groups 3 through 6:

Healthy children at least 8 months but less than 25 months of age whose LAR understands and signs the trial informed consent and agrees to vaccine administration following a detailed explanation of the trial.

Determined by medical history, targeted physical exam, and clinical judgement of the investigator to be in a good state of health. Screening laboratory values slightly outside lab normal ranges may be acceptable if the site investigator determines that they are not clinically significant. Permitted concomitant medications include nutritional supplements, medications for gastroesophageal reflux, eye drops, and topical medications, including topical steroids, topical antibiotics, and topical antifungal agents.

Sero- OR sero+ for RSV antibody, defined by serum RSV antibody titer assay not more than 30 days prior to vaccination.

Participant is expected to be available for the duration of the trial.

The LAR confirms that subject has received routine immunizations appropriate for age based on the current Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger.

Growing normally for age as demonstrated on a World Health Organization (WHO) growth chart, AND

If <1 year of age: has a current height and weight above the 5th percentile for age.

If ≥1 year of age: has a current height and weight above the 3rd percentile for age.

Subject Exclusion Criteria

<8 months of age and >60 months of age at the time of planned vaccine inoculation.

Born at less than 34 weeks gestation for subjects ≥ 1 year of age at enrollment

Born at less than 37 weeks gestation, and at the date of inoculation less than 1 year of age.

Maternal history of a positive HIV test before or during pregnancy.

Maternal history of illicit drug abuse or alcohol abuse.

Evidence of chronic disease except for chronic diseases that are mild, stable and not immune compromising or require recent change (< 60 days) in management (e.g., mild stable eczema, mild allergic rhinitis)

Clinically significant pulmonary, cardiovascular, hepatic or renal functional abnormality as determined by medical history or physical exam. Abnormal pulse oximetry testing during screening for undetected critical congenital heart disease or concern for such by medical history or physical exam.

Acute or chronic medical condition or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgement, make the participant inappropriate for the study.

History of severe infection (e.g., requiring hospitalization)

History of severe infection (e.g., requiring hospitalization).

Known or suspected impairment of immunological functions, bone marrow/solid organ transplant recipients.

Receiving immunosuppressive therapy including systemic corticosteroids.

Major congenital malformations, including congenital cleft palate or cytogenetic abnormalities.

Suspected or documented developmental disorder, delay, or other developmental problem.

Cardiac abnormality requiring treatment. Participants with clinically insignificant cardiac abnormalities (e.g., clinically insignificant patent foramen ovale) requiring no treatment may be enrolled.

Lung disease or reactive airway disease.

History of wheezing episode/s or receipt of bronchodilator therapy

Previous receipt of supplemental oxygen therapy in a home setting.

History of severe RSV infection or severe respiratory virus infection (e.g., requiring hospitalization).

Previous immunization with an investigational RSV vaccine.

Previous or planned administration of any anti-RSV antibody product within 6 months of receipt of study vaccine.

Previous receipt of immunoglobulin or any other antibody products within the past 6 months.

Previous receipt of any blood products within the past 6 months.

Previous anaphylactic reaction.

Previous serious vaccine-associated adverse reaction or one that was Grade 3 or above.

Known hypersensitivity to any study vaccine product component.

Household contact with any of the following groups of individuals for the period up to 28 days after vaccination (including after each dose for cohorts receiving two doses of vaccine):

Member of a household that contains an infant who is less than 6 months of age at the date of inoculation through the 28th day after inoculation. In groups assigned to two doses of vaccine, to include date of inoculation through the 28th day after the second inoculation.

Pregnant woman.

Persons with hospitalization for asthma or other chronic respiratory disease in the past 5 years.

Member of a household that, at the date of inoculation through the 28th day after inoculation (including second dose if scheduled), contains an immunocompromised individual including but not limited to:

A person who is HIV-infected.

A person who has cancer and has received chemotherapy within the 12 months prior to enrollment.

A person with a solid organ or bone marrow transplant.

A person currently receiving immunosuppressive agents.

Attends a daycare facility that does not separate children by age and contains an infant

<6 months of age at the date of inoculation through the 28th day after inoculation.

Neurological and neurodevelopmental conditions (e.g., cerebral palsy, epilepsy, stroke, seizures).

History of postinfectious or postvaccine neurological sequelae.

Autoimmune, inflammatory, vascular, or rheumatic disease.

Household contact of another child enrolled into the trial.

Inadequate venous access for repeated phlebotomy.

Subject's LAR/s who, in the opinion of the site investigator, are not suitable participants for the study, for any reason not previously delineated, including subjects with any condition that would in the opinion of the site investigator place the subject at unacceptable risk of injury or render the subject unable to meet the requirements of the protocol.

Subjects testing positive for infection with RSV, Influenza, or SARS-CoV-2 in the 3 months prior to enrollment.

Planned receipt of any of the following prior to planned trial vaccine receipt (Day 1 and Day 57 for group receiving 2 doses of vaccine):

Inactivated influenza vaccine within 14 days prior, or

Any other inactivated vaccine or live-attenuated rotavirus vaccine within the 14 days prior, or

Any live vaccine, other than rotavirus vaccine, within the 28 days prior, or

Another investigational vaccine or investigational drug within 28 days prior.

Salicylate (aspirin) or salicylate-containing products within 28 days prior

Salicylate (aspirin) or salicylate-containing products within 28 days prior.

Planned receipt of any of the following after planned trial vaccine receipt (Day 1 and Day 57 for groups receiving 2 doses of vaccine):

Inactivated vaccine or live-attenuated rotavirus vaccine within the 14 days after, or

Any live vaccine other than rotavirus in the 28 days after, or

Another investigational vaccine or investigational drug in the 56 days after.

Planned receipt of any of the following medications within 7 days of trial enrollment and 7 days after trial vaccine (Day 1 and also Day 57 for groups receiving 2 doses of vaccine):

Systemic antibacterial, antiviral, antifungal, anti-parasitic, or antituberculous agents, whether for treatment or prophylaxis, or systemic or nasal steroid therapy for acute illness.

Any other intranasal medications, or

Other prescription medications except permitted concomitant medications. Permitted concomitant medications (prescription or non-prescription) include nutritional supplements, medications for gastroesophageal reflux, eye drops, and topical medications, including (but not limited to) cutaneous (topical) steroids, topical antibiotics, and topical antifungal agents.

History of bleeding disorder or significant problem with bleeding

American Indian or Alaska Native Infants/Children (high risk for severe RSV infection) AND eligible to receive nirsevimab

Temporary exclusion criteria for sero+ children, sero- children, and infants:

The following are temporary or self-limiting conditions, and once resolved, the subject may be enrolled, if otherwise eligible. If the period of temporary exclusion is greater than 30 days, sero- children will need to be rescreened for levels of RSV neutralizing antibody.

Any of the following events at the time of enrollment:

Fever (temperature of ≥100.4°F per site standard based on age; e.g., oral for older children, rectal for infants, axillary screening), or

Upper respiratory signs or symptoms (rhinorrhea, cough, or pharyngitis) or

Nasal congestion significant enough to interfere with successful vaccination.

Otitis media.

Contact with a person diagnosed with RSV, Influenza, coronavirus disease-2 (COVID- 19) or other viral respiratory illnesses within the preceding 10 days.

Conditions & Interventions

Interventions:
BIOLOGICAL: PIV5-vectored RSV Vaccine (BLB-201) Low Dose, BIOLOGICAL: PIV5-vectored RSV Vaccine (BLB-201) High Dose, DRUG: Placebo
Conditions:
Respiratory Syncytial Virus Infections
Keywords:
Human respiratory syncytial virus (RSV), Lower respiratory tract infection (LRTI)

More Information

Description:
This Phase 1/2a trial is a randomized, placebo-controlled trial to evaluate the safety, tolerability and immunogenicity of two ascending doses (10\^6 PFU and 10\^7 PFU) of intranasal BLB-201 (a recombinant parainfluenza virus type 5) administered in infants (8-24 months of age) and children (18-59 months of age) who may or may not have had prior respiratory syncytial virus (RSV) infection.

Contact(s): Jamie Kidd - jamie.kidd@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE1
IRB Number:
System ID: NCT05655182