Safety of RSV Preventive Monoclonal Antibody

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 weeks to 30 weeks old
Healthy Volunteers: This study is also accepting healthy volunteers
Inclusion Criteria:

- Infants ≥ 6 weeks to <30 weeks of age at the time of enrollment
- Infants eligible for RSV monoclonal antibody and at least one routine childhood vaccine in outpatient clinic
- The parent/legal guardian must be willing and capable of providing permission for their infant to participate through the written informed consent process
- Parent/legal guardian must be able to read and comprehend English or Spanish
- The parent/legal guardian must be available for follow-up study contact by telephone from enrollment to completion of the study period
- The parent/legal guardian must agree to sign a medical record release for the infant so that study personnel may obtain medical information about the infant's health (if needed)
- The parent/legal guardian must be willing to delay their child's receipt of RSV monoclonal antibody up to two weeks from the scheduled date and to return for a second visit to receive the deferred RSV monoclonal antibody

Exclusion Criteria:

- Known contraindication or precaution to RSV monoclonal antibody or other routine vaccines being administered
- Received any vaccine within 14 days prior to enrollment and the first immunization day in this study
- Known previous receipt of RSV monoclonal antibody
- Received any experimental/investigational agent (vaccine, drug, biologic, device, blood product, or medication) within 28 days prior to immunization in this study or expects to receive an experimental/investigational agent within the follow-up time period (8 days after the second immunization in this study)
- A moderate to severe acute illness and/or a reported temporal temperature greater than or equal to 100.4°F (38.0°C) within 48 hours prior to enrollment or a temporal temperature (measured by temporal artery thermometer) greater than or equal to 100.4°F (38.0°C) at the time of enrollment. (This may result in a temporary delay of immunization)
- Receipt of an antipyretic medication (acetaminophen or ibuprofen) within 48 hours prior to enrollment (This may result in a temporary delay of immunization)
- Planned receipt of a prophylactic antipyretic medication on the day of and/or days following immunization. This exclusion does not apply if the parent/legal guardian indicates they might administer antipyretics after immunization in response to fever or pain
- Has any condition that would, in the opinion of the site investigator, place the participant at an unacceptable risk of injury or render the participant unable to meet the requirements of the protocol
- Anyone who is a first-degree relative of any research study personnel
- The infant is born to a mother who received a maternal RSV immunization more than 14 days prior to delivery and is not eligible for RSV preventative monoclonal antibody
- Bleeding disorder or condition associated with prolonged bleeding that would present as a safety risk per opinion of the investigator
- History of severe adverse reaction associated with a vaccine and/or severe allergic reaction to any component of the vaccines or RSV monoclonal antibody
- Has an active neoplastic disease, or a history of any hematologic malignancy
- History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a vaccine administered on the day of study enrollment
- Immunosuppression as a result of an underlying illness or treatment or use of anti-cancer chemotherapy or radiation therapy since birth
- For infants receiving DTaP vaccine (alone or combination vaccine): Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTaP
- Intention to receive non-live or live vaccines during the 4 weeks after Visit 1; vaccines may be administered after enrollment if deemed a personal or public health priority by the health care provider caring for this patient or the study team
- Long term (at least 14 days of prednisone 2 mg/kg/day or equivalent other glucocorticoid) use of any parenteral steroids within the 6 months prior to enrollment (topical, nasal and inhaled steroids are allowed)

Conditions & Interventions

Interventions:
DRUG: Respiratory Syncytial Virus (RSV) Preventive Monoclonal Antibody
Conditions:
Fever, Adverse Event Following Immunisation
Keywords:
Respiratory Syncytial Virus (RSV), Fever Following Immunization, RSV Monoclonal Antibody

More Information

Description:
This is a prospective, randomized, open-label clinical trial to evaluate the safety of administration of respiratory syncytial virus (RSV) preventive

This is a prospective, randomized, open-label clinical trial to evaluate the safety of administration of respiratory syncytial virus (RSV) preventive monoclonal antibody and other routine childhood vaccines given simultaneously at Visit 1, as compared to sequential administration of respiratory syncytial virus (RSV) preventive monoclonal antibody and other vaccines at separate visits (Visits 1 and 2).

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