

Safety of RSV Preventive Monoclonal Antibody

NCT07158814

Status	RECRUITING
Phase	Phase 4
Sponsor	Duke University
Enrollment	524 participants

Key Eligibility Criteria

Inclusion (7)

- 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

... and 2 more (see full listing online)

Exclusion (18)

- 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)

... and 13 more (see full listing online)

Locations (6 total)

Kaiser Permanente Northern California, Oakland, California, United States
Emory University, Atlanta, Georgia, United States
Centers for Disease Control and Prevention, Atlanta, Georgia, United States
... and 3 more locations

<https://clinicaltrials.gov/study/NCT07158814>

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