

Record 7 of 9



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Completed

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A Study to Evaluate the Safety, Tolerability and Immunogenicity of V114 in Healthy Adults and Infants (V114-005)

ClinicalTrials.gov ID *i* NCT02531373

Sponsor *i* Merck Sharp & Dohme LLC

Information provided by *i* Merck Sharp & Dohme LLC (Responsible Party)

Last Update Posted *i* 2019-04-02

Record History Tab

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
 - To view one version of the study record, click the submitted date.
 - To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2015-08-20	None (earliest version on record)

Feedback

	Version	Date submitted (YYYY-MM-DD)	Changes
			• Contacts/Locations
☐	3	2015-09-22	• Study Status • Contacts/Locations
☐	4	2015-10-20	• Study Status • Contacts/Locations
☐	5	2015-11-03	• Study Status • Contacts/Locations
☐	6	2015-11-11	• Study Status • Contacts/Locations
☐	7	2015-12-17	• Study Status • Contacts/Locations
☐	8	2016-01-21	• Study Status • Contacts/Locations
☐	9	2016-02-04	• Study Status
☐	10	2016-03-10	• Recruitment Status • Study Status • Contacts/Locations
☐	11	2016-05-17	• Study Status
☐	12	2016-07-18	• Study Status
☐	13	2016-08-29	• Study Status
☐	14	2016-10-30	• Study Status
☐	15	2017-01-18	• Study Status
☐	16	2017-03-20	• Study Status
☐	17	2017-05-08	• Recruitment Status

	Version	Date submitted (YYYY-MM-DD)	Changes
			• Study Status • Study Design
☐	18	2018-03-16	• Study Status • Oversight • Arms and Interventions • Outcome Measures • Document Section • Participant Flow • Baseline Characteristics • Outcome Measures (Results) • Adverse Events • More Information
☐	19	2018-05-11	• Study Status • Outcome Measures • Participant Flow • Baseline Characteristics • Outcome Measures (Results)
☐	20	2018-10-01	• Study Status • IPDSharing
☐	21	2019-03-21	• Study Status • IPDSharing • References



Viewing **V5** (2015-11-03)

Study Details

Study Identification

Unique Protocol ID

V114-005

Brief Title

A Study to Evaluate the Safety, Tolerability and Immunogenicity of V114 in Healthy Adults and Infants (V114-005)

Official Title

A Phase I-II, Randomized, Double-Blind, Study to Evaluate the Safety, Tolerability, and Immunogenicity of Different Formulations of V114 in Healthy Adults and Infants

Secondary IDs

Study Status

Record Verification

2015-11

Overall Status

Recruiting

Study Start

2015-09

Primary Completion

2017-09 [Estimated]

Study Completion

2017-09 [Estimated]

First Submitted

2015-08-20

First Submitted that Met QC Criteria

2015-08-20

First Posted

2015-08-24 [Estimated]

Last Update Submitted that Met QC Criteria

2015-11-03

Last Update Posted

2015-11-04 [Estimated]

Sponsor/Collaborators**Sponsor**

Merck Sharp & Dohme LLC

Responsible Party

Sponsor

Collaborators**Oversight****U.S. FDA-regulated Drug****U.S. FDA-regulated Device****Data Monitoring**

Yes

Study Description

Brief Summary

This study is designed to assess the effect of different dose levels of pneumococcal polysaccharide and adjuvant on the safety and immunogenicity of V114 in healthy adults and infants.

Detailed Description

Conditions

Condition

Pneumococcal Infections

Keywords

Study Design

Study Type

Interventional

Primary Purpose

Prevention

Study Phase

Phase 1

Phase 2

Interventional Study Model

Parallel Assignment

Number of Arms

9

Masking

Triple (Participant, Care Provider, Investigator)

Allocation

Randomized

Enrollment

330 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Adult: V114 Medium Dose Adult participants will receive a single 0.5 mL intramuscular injection of medium-dose V114 on Day 1.	Biological: V114 Medium Dose Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), serotype 6B (4 mcg) and Merck Aluminum Phosphate Adjuvant (125 mcg) in each 0.5 mL dose
Experimental: Adult: V114 High Dose Adult participants will receive a single 0.5 mL intramuscular injection of high-dose V114 on Day 1.	Biological: V114 High Dose Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (4 mcg each), serotype 6B (8 mcg), and Merck Aluminum Phosphate Adjuvant (250 mcg) in each 0.5 mL dose
Experimental: Adult: V114 Medium Dose with Alternative Carrier Protein Adult participants will receive a single 0.5 mL intramuscular injection of medium-dose V114 with alternative carrier protein on Day 1.	Biological: V114 Medium Dose with Alternative Carrier Protein Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), serotype 6B (4 mcg), and Merck Aluminum Phosphate Adjuvant (125 mcg) with alternative carrier protein in each 0.5 mL dose

Experimental: Adult: V114 High Dose with Alternative Carrier Protein Adult participants will receive a single 0.5 mL intramuscular injection of high-dose V114 with alternative carrier protein on Day 1.	Biological: V114 High Dose with Alternative Carrier Protein Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (4 mcg each), serotype 6B (8 mcg), and Merck Aluminum Phosphate Adjuvant (250 mcg) with alternative carrier protein in each 0.5 mL dose
Experimental: Infant: V114 Medium Dose Infant participants will receive a 0.5 mL intramuscular injection of medium-dose V114 at 2, 4, 6, and 12 to 15 months of age.	Biological: V114 Medium Dose Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), serotype 6B (4 mcg) and Merck Aluminum Phosphate Adjuvant (125 mcg) in each 0.5 mL dose
Experimental: Infant: V114 High Dose Infant participants will receive a 0.5 mL intramuscular injection of high-dose V114 at 2, 4, 6, and 12 to 15 months of age.	Biological: V114 High Dose Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (4 mcg each), serotype 6B (8 mcg), and Merck Aluminum Phosphate Adjuvant (250 mcg) in each 0.5 mL dose
Experimental: Infant: V114 Medium Dose with Alternative Carrier Protein Infant participants will receive a 0.5 mL intramuscular injection of medium-dose V114 with alternative carrier protein at 2, 4, 6, and 12 to 15 months of age.	Biological: V114 Medium Dose with Alternative Carrier Protein Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), serotype 6B (4 mcg), and Merck Aluminum Phosphate Adjuvant (125

	mcg) with alternative carrier protein in each 0.5 mL dose ▲
Experimental: Infant: V114 High Dose with Alternative Carrier Protein Infant participants will receive a 0.5 mL intramuscular injection of high-dose V114 with alternative carrier protein at 2, 4, 6, and 12 to 15 months of age.	Biological: V114 High Dose with Alternative Carrier Protein Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (4 mcg each), serotype 6B (8 mcg), and Merck Aluminum Phosphate Adjuvant (250 mcg) with alternative carrier protein in each 0.5 mL dose
Active Comparator: Infant: Pevnar 13™ Infant participants will receive a 0.5 mL intramuscular injection of Pevnar 13™ at 2, 4, 6, and 12 to 15 months of age.	Biological: Pevnar 13™ Pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F (2.2 mcg) and 6B (4.4 mcg) in each 0.5 ml dose

Outcome Measures

Primary Outcome Measures

- Percentage of Participants with an Adverse Event (Adult Participants)
[Time Frame: Up to 1 month after vaccination]
- Percentage of Participants with an Adverse Event (Infant Participants)
[Time Frame: Up to 1 month after Dose 4 (up to 14 months)]
- Percentage of Participants who Discontinued the Study Due to an Adverse Event (Infant Participants)
[Time Frame: Up to 1 month after Dose 4 (up to 14 months)]
- Percentage of Participants with a Solicited Injection-site Adverse Event (Infant)
[Time Frame: Up to 1 month after Dose 4 (up to 14 months)]
- Percentage of Participants with a Solicited Systemic Adverse Event (Infant Participants)
[Time Frame: Up to 1 month after Dose 4 (up to 14 months)]

6. Geometric Mean Concentration of Serotype-specific Pneumococcal Antibody (Infant Participants)
[Time Frame: One month after Dose 3 (5 months)]

Secondary Outcome Measures

1. Geometric Mean Concentration of Serotype-specific Pneumococcal Antibody (Adult Participants)
[Time Frame: One month after vaccination]
2. Geometric Mean Fold-rise from Baseline of Serotype-specific Pneumococcal Antibody (Adult Participants)
[Time Frame: Baseline and 1 month after vaccination]
3. Percentage of Participants Achieving the Serotype-specific Threshold Value of ≥ 0.35 mcg/mL at One Month after Dose 3 (Infant participants)
[Time Frame: One month after Dose 3 (5 months)]
4. Percentage of Participants Achieving the Serotype-specific Threshold Value of ≥ 0.35 mcg/mL before Dose 4 (Infant participants)
[Time Frame: Before Dose 4 (10 to 13 months)]
5. Percentage of Participants Achieving the Serotype-specific Threshold Value of ≥ 0.35 mcg/mL at One Month after Dose 4 (Infant participants)
[Time Frame: One month after Dose 4 (11 to 14 months)]
6. Geometric Mean Concentration of Serotype-specific Pneumococcal Antibody before Dose 4 (Infant Participants)
[Time Frame: Before Dose 4 (10 to 13 months)]
7. Geometric Mean Concentration of Serotype-specific Pneumococcal Antibody at One Month After Dose 4 (Infant Participants)
[Time Frame: One month after Dose 4 (11 to 14 months)]

Eligibility

Minimum Age

2 Months

Maximum Age

49 Years

Sex

All

Gender-based Eligibility

Gender Eligibility Description

Accepts Healthy Volunteers

Yes

Criteria

Inclusion Criteria:

Adult Cohort: 18 to 49 years and in good health

- Highly unlikely to conceive from vaccination through 6 weeks after administration of the study vaccine.

Infant Cohort: approximately 2 months (42 to 90 days) and in good health.

Exclusion Criteria:

Adult cohort: Prior administration of any pneumococcal vaccine

- History of invasive pneumococcal disease
- Known hypersensitivity to any vaccine component
- Known or suspected impairment of immune function
- Coagulation disorder contraindicating intramuscular vaccination
- Received a blood transfusion or blood products within 6 months
- Participated in another clinical study of an investigational product within 2 months
- Breast feeding. Infant cohort: Prior administration of any pneumococcal vaccine
- Known hypersensitivity to any vaccine component
- Known or suspected impairment of immune function
- History of congenital or acquired immunodeficiency
- Has or mother has documented Human Immunodeficiency virus (HIV) infection
- Has or mother has documented hepatitis B surface antigen positive result
- Functional or anatomic asplenia
- History of failure to thrive
- Coagulation disorder contraindicating intramuscular vaccination
- History of autoimmune disease or autoimmune disorder
- Known neurologic or cognitive behavioral disorder
- Received systemic corticosteroids within 14 days
- Received other licensed non-live vaccine within 14 days

- Received other licensed live virus vaccine within 30 days
- Received a blood transfusion or blood products
- Participated in another clinical study of an investigational product
- History of invasive pneumococcal disease

Contacts/Locations

Central Contact Person

- Name
Toll Free Number

Telephone
1-888-577-8839

Study Officials

- Name
Medical Director

Role
Study Director

Affiliation
Merck Sharp & Dohme LLC

Location

- **Galveston, Texas, United States, 77555**
Status:
Recruiting

Facility:
Call for Information (Investigational Site 0004)
- **San Antonio, Texas, United States, 78229**
Status:
Recruiting

Facility:
Call for Information (Investigational Site 0001)

IPD Sharing

IPD information

References

Citations

Links

Available IPD/Information

Document Section

[HHS Vulnerability Disclosure](#)