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Protocol Registration and Results Preview

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Post-marketing Evaluation of Reactions Following Receipt of Recommended Adolescent Pertussis Vaccine

This study has been completed.

Sponsor:	Sanofi Pasteur, a Sanofi Company
Collaborators:	
Information provided by (Responsible Party):	Sanofi (Sanofi Pasteur, a Sanofi Company)
ClinicalTrials.gov Identifier:	NCT00304265

Purpose

Post-marketing evaluation of reactions following receipt of recommended adolescent pertussis vaccine among persons with prior vaccination with acellular vs whole-cell pertussis vaccine.

To describe and characterize adverse events occurring after vaccination with REPEVAX® (Tdap-IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine among two groups: Group 1 - adolescents 10-14 years of age who participated in study 371-03/01 (and thus received a 5th dose of TRIPEDIA® vaccine) and Group 2 - controls 10 -14 years of age who were vaccinated with at least three doses of a whole-cell pertussis vaccine in infancy plus at least one subsequent dose of pertussis vaccine in their 2nd through 7th year of life.

Condition	Intervention	Phase
Pertussis Diphtheria	Biological/Vaccine: COVAXIS™: Tetanus, diphtheria, acellular 5-component pertussis, or + inactivated poliovirus vaccine (REPEVAX®)	Phase 4

Tetanus Poliomyelitis		

Study Type: Interventional
Study Design: Prevention, Parallel Assignment, Open Label, Randomized, Safety Study

Official Title: Reactogenicity of Acellular Pertussis Vaccine Booster in Adolescents Who Have Received 5 Prior Doses of BIKEN Acellular Pertussis Vaccine in Combination With Diphtheria and Tetanus Toxoids (TRIPEDIA®) or Who Have Received Primary Vaccination With 3 Doses of Whole-Cell Pertussis Vaccine, Plus at Least 1 Pertussis Booster Vaccination

Further study details as provided by Sanofi (Sanofi Pasteur, a Sanofi Company):

Primary Outcome Measure:

- Number of Participants Reporting a Solicited Local or Systemic Reaction Post-Vaccination With Either REPEVAX® or COVAXIS® Vaccine [Time Frame: Days 0 to 14 Post-vaccination] [Designated as safety issue: No]

  Solicited injection site reactions: Pain, Erythema, Swelling, and Arm circumference. Solicited systemic reactions: Fever (temperature), Headache, Malaise, and Myalgia.

Enrollment: 215
Study Start Date: March 2006
Study Completion Date: October 2007
Primary Completion Date: October 2006

Arms	Assigned Interventions
Experimental: 6th Dose Pertussis Vaccine Group Participants received 6th dose of pertussis vaccine	Biological/Vaccine: COVAXIS™: Tetanus, diphtheria, acellular 5-component pertussis, or + inactivated poliovirus vaccine (REPEVAX®) 0.5 mL, Intramuscular Other Names: • REPEVAX® • COVAXIS™ • IPV Merieux™
Experimental: 5th Dose Pertussis Vaccine Group Participants received 5th dose of pertussis vaccine	Biological/Vaccine: COVAXIS™: Tetanus, diphtheria, acellular 5-component pertussis, or + inactivated poliovirus vaccine (REPEVAX®) 0.5 mL, Intramuscular Other Names: • REPEVAX® • COVAXIS™ • IPV Merieux™

Eligibility

Ages Eligible for Study: 10 Years to 14 Years
Genders Eligible for Study: Both
Accepts healthy volunteers.
Inclusion Criteria:

- Eligible to receive REPEVAX® or COVAXIS® vaccine, in accord with German recommendations for a booster dose of acellular pertussis vaccine at 9-17 years of age.
- Signed and dated informed consent or assent form (as applicable) that is obtained prior to the first study intervention.
- Judged to be in good health on the basis of reported medical history and history-directed physical examination.
- Plans to remain in the study area for the length of the trial.
- The participant and a parent or legal guardian can read, write, and understand the documents and all are mentally competent to give assent and consent.

- If female, not known or suspected to be pregnant at the time of enrollment into the study and is not planning pregnancy during participation in this trial.
- Either prior participation in study 371-03/01 (Group 1 - 6th Dose Pertussis Vaccine Group) or a documented history of 3 doses of tetanus, diphtheria and whole-cell pertussis vaccine in infancy plus at least one subsequent dose of pertussis vaccine in their 2nd through 7th year of life (Group 2 - 5th Dose Pertussis Vaccine Group).
- Has access to a telephone.
- Oral temperature < 38.0ºC.

Exclusion Criteria:

- Pregnancy or nursing a child
- Known or suspected primary or acquired disease of the immune system (conditions suspected of having an immunologic component such as autoimmune diseases [e.g. rheumatoid arthritis or inflammatory bowel disease] will not be excluded unless they meet exclusion criterion 3 or 5).
- Malignancy, allergy immunotherapy, or receiving immunosuppressive therapy (participants who are taking topical and inhaled steroids could be included in the study as would participants on a "short course" of oral steroids, -<7 days, as long as there are not two courses within the previous two weeks prior to vaccination).
- Receipt of any pertussis, diphtheria or tetanus-containing vaccines within the past 3 years.
- Any unstable significant underlying chronic disease, including (but not limited to) malignancy, cardiopulmonary disease, renal, endocrinologic, hematologic or hepatic dysfunction.
- Known impairment of neurologic function or currently active seizure disorder or currently requiring medication for seizures.
- Personal history of physician-diagnosed or laboratory-confirmed pertussis disease within the last 2 years.
- Receipt of blood products or immunoglobulin within the previous 3 months.
- Known or suspected allergy to any of the vaccines or vaccine components intended for use in the study.
- Daily use of non-steroidal anti-inflammatory drugs.
- Receipt of any vaccine or investigational product within the 30 days prior to enrollment, or planning to receive another vaccine within 28 days after receiving study vaccine.
- Chemical dependency (e.g. alcoholism or intravenous drug use but not including nicotine or caffeine), based on investigator judgment.
- Known or suspected acute infectious respiratory illness at the time of vaccination with active symptoms and signs including one or more of the following: rhinorrhea, new cough, pharyngitis, respiratory problems (e.g. wheezing, shortness of breath).

- Any condition which, in the opinion of the investigator, would pose a health risk to the participant or interfere with the evaluation of the vaccine.
- History of immediate anaphylaxis, encephalopathy within 7 days, or seizure within 3 days of receiving diphtheria, tetanus, or pertussis vaccine.
- Planned participation in another interventional clinical trial during the present trial period (participation in a related study to evaluate immune responses to this study's vaccination is permitted).
- Thrombocytopenia or bleeding disorder that would pose a contraindication to an intramuscular (IM) vaccination.

Contacts and Locations

Locations

Germany

Bielefeld, Germany, D-33611

Detmold, Germany, D-32756

Donzdorf, Germany, D-73072

Grafing, Germany, D-85567

Heilbronn, Germany, D-74072

Lauffen, Germany, D-74348

Marbach, Germany, D-71672

Marktoberdorf, Germany, D-87616

Munich, Germany, D-80939

Munich, Germany, D-81247

Schwandorf, Germany, D-92421

Schwieberdingen, Germany, D-71701

Schwäbisch Hall, Germany, D-74523

Stuttgart, Germany, D-70469

Süßen, Germany, D-73079

Veitshöchheim, Germany, D-97209

Munich, Lindwurmstrasse 4, Germany, D-80337

Investigators

Study Director: Medical Director Sanofi Pasteur Inc.

More Information

Related Info

Related Info

Results Publications:

Liese JG, Rieber N, Malzer T, Ocak M, Johnson DR, Decker MD; Munich Vaccine Study Group. Reactogenicity of tetanus, diphtheria, 5-component acellular pertussis vaccine administered as a sixth consecutive acellular pertussis vaccine dose to adolescents. Pediatr Infect Dis J. 2010 Dec;29(12):1067-71.

Responsible Party: Sanofi Pasteur, a Sanofi Company
Study ID Numbers: TRI05
Health Authority: Germany: Paul-Ehrlich-Institut

Study Results

Participant Flow

Recruitment Details	Participants were enrolled from February 2006 to July 2006 at 17 clinical sites in Germany.
Pre-Assignment Details	A total of 214 participants who met the inclusion and exclusion criteria were enrolled and vaccinated. One over aged participant was also vaccinated and included in the safety analysis.

Arm/Group Title	6th Dose Pertussis Vaccine Group	5th Dose Pertussis Vaccine Group	Total (Not public)
Arm/Group Description	Participants who had received 5 doses of BIKEN acellular pertussis vaccine in Study 371-03/01 received REPEVAX® (Tdap-IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine as a 6th (booster) dose as adolescents.	Participants who had received at least 3 doses of whole-cell pertussis vaccine during infant immunization and at least 1 subsequent booster vaccination in the 2nd to 7th years of life received either REPEVAX® (Tdap-IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine as a 5th (booster) dose as adolescents.	

Period Title: **Overall Study**			
Started	117	98	215
Completed	117	98	215
Not Completed	0	0	0

Baseline Characteristics

Arm/Group Title	6th Dose Pertussis Vaccine Group	5th Dose Pertussis Vaccine Group	Total
Arm/Group Description	Participants who had received 5 doses of BIKEN acellular pertussis vaccine in Study 371-03/01 received REPEVAX® (Tdap-IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine as a 6th (booster) dose as adolescents.	Participants who had received at least 3 doses of whole-cell pertussis vaccine during infant immunization and at least 1 subsequent booster vaccination in the 2nd to 7th years of life received either REPEVAX® (Tdap-IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine as a 5th (booster) dose as adolescents.	
Overall Number of Baseline Participants	117	98	**215**
Baseline Analysis Population Description			

[Not specified]			
Age, Categorical Measure Type: Number Units: Participants			
<=18 years	117	98	215
Between 18 and 65 years	0	0	0
>=65 years	0	0	0
Age, Continuous Mean (Full Range) Units: Years	12.3 (11 to 13)	12.6 (10 to 16)	12.4 (10 to 16)
Gender, Male/Female Measure Type: Number Units: Participants			
Female	55	37	92
Male	62	61	123
Region of Enrollment Measure Type: Number Units: Participants			
Germany	117	98	215

Outcome Measures

1. Primary Outcome

Title:	Number of Participants Reporting a Solicited Local or Systemic Reaction Post-Vaccination With Either REPEVAX® or COVAXIS® Vaccine
Description:	Solicited injection site reactions: Pain, Erythema, Swelling, and Arm circumference. Solicited systemic reactions: Fever (temperature), Headache, Malaise, and Myalgia.
Time Frame:	Days 0 to 14 Post-vaccination
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Safety analysis was on all enrolled and vaccinated participants with available reaction data, intent-to-treat population.

Arm/Group Title	6th Dose Pertussis Vaccine Group	5th Dose Pertussis Vaccine Group
▼ Arm/Group Description:	Participants who had received 5 doses of BIKEN acellular pertussis vaccine in Study 371-03/01 received REPEVAX® (Tdap-IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine as a 6th (booster) dose as adolescents.	Participants who had received at least 3 doses of whole-cell pertussis vaccine during infant immunization and at least 1 subsequent booster vaccination in the 2nd to 7th years of life received either REPEVAX® (Tdap -IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine as a 5th (booster) dose as adolescents.
Number of Participants Analyzed	117	97
Measure Type: Number Units: Participants		
Any Local Reactions After Vaccination	89	87
Any Pain	85	87
Grade 3 Pain (Incapacitating)	7	8
Any Erythema	19	27
Grade 3 Erythema (> 5.0 cm)	10	10
Any Swelling	24	17

Grade 3 Swelling (> 5.0 cm)	6	8
Any Increase in Arm Circumference	8	11
Grade 3 Increase in Arm Circumference (> 5.0 cm)	0	0
Any Systemic Reactions After Vaccination	85	84
Fever	5	15
Any Headache	40	50
Grade 3 Headache (Prevents Daily Activities)	4	5
Any Malaise	40	44
Grade 3 Malaise (Prevents Daily Activities)	2	2
Any Myalgia	69	73
Grade 3 Myalgia (Prevents Daily Activity)	5	10

Adverse Events

Time Frame	Adverse event data were collected for 28 days post-vaccination.	
Additional Description		
Source Vocabulary Name	MedDRA 6.0	
Assessment Type	Non-systematic Assessment	
Arm/Group Title	6th Dose Pertussis Vaccine Group	5th Dose Pertussis Vaccine Group

▼ Arm/Group Description	Participants who had received 5 doses of BIKEN acellular pertussis vaccine in Study 371-03/01 received REPEVAX® (Tdap-IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine as a 6th (booster) dose as adolescents.	Participants who had received at least 3 doses of whole-cell pertussis vaccine during infant immunization and at least 1 subsequent booster vaccination in the 2nd to 7th years of life received either REPEVAX® (Tdap-IPV: combination diphtheria, tetanus and acellular pertussis with inactivated poliomyelitis vaccine) or COVAXIS® (Tdap: combination diphtheria, tetanus and acellular pertussis) vaccine as a 5th (booster) dose as adolescents.

▼ Serious Adverse Events

	6th Dose Pertussis Vaccine Group	5th Dose Pertussis Vaccine Group
	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/117 (0%)	0/98 (0%)

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5.0%	
	6th Dose Pertussis Vaccine Group	**5th Dose Pertussis Vaccine Group**
	Affected / at Risk (%)	Affected / at Risk (%)
Total	89/117 (76.07%)	87/97 (89.69%)
General dis... Injection site pain †	89/117 (76.07%)	87/97 (89.69%)
General dis...	19/117 (16.24%)	27/97 (27.84%)

	Injection site erythema †		
General dis...	Injection site swelling †	24/117 (20.51%)	17/97 (17.53%)
Nervous sys...	Headache †	40/117 (34.19%)	50/97 (51.55%)
General dis...	Malaise †	40/117 (34.19%)	44/97 (45.36%)
Musculoskel...	Myalgia †	69/117 (58.97%)	73/97 (75.26%)
General dis...	Pyrexia †	5/117 (4.27%)	15/97 (15.46%)

† Indicates events were collected by systematic assessment.

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Sponsor must have the opportunity to review at least 60 days prior to submission for publication or presentation. If review indicates that potentially patentable subject matter would be disclosed, publication or public disclosure may be delayed for a maximum of an additional 60 days to allow for filing the necessary patent applications.

Results Point of Contact

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