TCTR ID : TCTR20190927006

OTHER ID :

Overall Recruitment Status : Completed **(No Results)**

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date :	27 September 2019
First Posted Date :	27 September 2019
Last Update Posted Date :	11 October 2023

Title

Public Title :	Safety and Antibody Responses in Adults and Elderly after Immunization with a Recombinant Pertussis Booster Dose
Acronym :	TDA206
Scientific Title :	A phase III randomized, observer-blind, active-controlled study to compare the safety and immunogenicity of an investigational combined Tetanus-diphtheria-recombinant acellular pertussis vaccine (BioNet Tdap) and licensed recombinant TdaP vaccine (Boostagen), investigational recombinant monovalent acellular pertussis vaccine (BioNet ap) and licensed recombinant aP vaccine (Pertagen), and another licensed Tdap vaccine, when administered to healthy adults aged of 18-75 years old
Sponsor ID/ IRB ID/ EC ID :	TDA206
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20190927006
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	COA No.063/2020
Date of Approval :	28 January 2020
Board Name :	Institutional Review Board
Board Affiliation :	Faculty of Medicine, Chulalongkorn University
Board Contact :	Business Phone : 022564493 Ext. N/A
	Business Email : medchulairb@chula.ac.th
	Business Address : 1873 Rama IV Road, Patumwan,Bangkok 10330,Thailand

Sponsor

Source(s) of Monetary or Material Supports :	Thai government Fund
Study Primary Sponsor :	Chulalongkorn University
Responsible Party :	Name/Official Title : Wassana Wijgkananlan
	Organization : BioNet-Asia Co., Ltd.
	Phone : 023618110 Ext. 271
	Email : wassana.w@bionet-asia.com
Study Secondary Sponsor :	BioNet-Asia Co., Ltd.

Protocol Synopsis

Protocol Synopsis :	This is a phase III, observer-blind, randomized, active controlled pertussis vaccine trial in which 750 healthy adults aged of 18-75 years old will be recruited from one study site in Thailand.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Pertussis vaccine
Keywords :	Pertussis vaccine

Eligibility

Inclusion Criteria :	1. Aged 18 to 64 years (less than 65 years full of age) or 65 to 75 years (less than 76 years full of age) on the day of inclusion;

2. Can provide written informed consent;
3. Healthy, as established by pertinent medical history and physical examination;
4. Capable of complying with the study protocol and procedures;
5. For women who have not had menopause, must have a negative urine pregnancy test at enrollment and willing to take reliable birth control measures for two months after vaccination.

Gender : Both

Age Limit : Minimum : 18 Years Maximum : 75 Years

Exclusion Criteria : 1. History of significant medical illness such as but not limited to immune deficiency, clinically significant psychiatric, hematologic, pulmonary, cardiovascular, or hepatic, renal, splenic or thymic functional abnormality as determined by the investigator based on medical history and physical examination that may interfere with the participations safety and the evaluation of investigational vaccines in this study;
2. Breastfeeding women or female participants who intend to become pregnant during the study period;
3. History of a severe allergic reaction to any vaccine (including its components);
4. History of serious adverse event or neurological adverse event to any vaccination;
5. Receipt of any investigational product or licensed vaccine within 30 days prior to enrollment (3 months for live-attenuated vaccines);
6. Plan to receive tetanus, diphtheria or pertussis vaccine or plan to participate in other clinical trial during the study period (approximately one year);
7. Having been experienced physician-diagnosed pertussis within 1 year prior to enrollment;
8. Receipt of diphtheria or tetanus or pertussis vaccine within 1 year prior to enrollment;
9. Any chronic or active neurologic disorder, including seizure, and epilepsy;
10. Has a known history of Guillain-Barr Syndrome;
11. Has an active malignancy or recent (<10 years) history of metastatic or hematologic malignancy;
12. Any bleeding disorder indicated;
13. Suspected or known alcoholism and/or illicit drug abuse within the past 5 years;
14. Administration of immunoglobulins and/or any blood products within 3 months preceding study entry or planned administration during the study period;
15. History of receiving immunosuppressive drugs or systemic corticosteroid (>0.5 mg/kg of prednisolone or equivalent for more than 14 days) within 3 months prior to study entry;
16. Has any active clinically significant finding or life-threatening disease that, in the opinion of the investigator, would increase the risk of the individual having an adverse outcome by participating in this study.

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Completed

Key Trial Dates		
	Study Start Date (First enrollment) : 10 February 2020	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 30 August 2021	Indicate Type : Actual
	Study Completion Date : 12 January 2023	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Prevention

Study Phase : Phase 3

Intervention Model : Parallel

Number of Arms : 5

Masking :

Allocation : Randomized

Control : Active

Study Endpoint Classification : Safety/Efficacy Study

Sample size

Planned sample size : 750

Actual sample size at study completion : 734

Intervantion Arm 1

Intervention name : BioNet ap

Intervention Type : Experimental

Intervention Classification : Biological/Vaccine

Intervention Description : Acellular pertussis (ap) vaccine given intramuscularly as a single dose (0.5 ml) on day 0

Intervantion Arm 2

Intervention name : BioNet Tdap

Intervention Type : Experimental

Intervention Classification : Biological/Vaccine

Intervention Description : Tetanus toxoid, diphtheria toxoid and medium dose of recombinant acellular pertussis vaccine given intramuscularly as a single dose (0.5 ml) on day 0

Intervantion Arm 3

Intervention name : Licensed aP

Intervention Type : Experimental

Intervention Classification : Biological/Vaccine

Intervention Description : Acellular pertussis (aP) vaccine given intramuscularly as a single dose (0.5 ml) on day 0

Intervantion Arm 4

Intervention name : Licensed TdaP

Intervention Type : Experimental

Intervention Classification : Biological/Vaccine

Intervention Description : Tetanus toxoid, diphtheria toxoid and recombinant acellular pertussis (TdaP) vaccine given intramuscularly as a single dose (0.5 ml) on day 0

Intervantion Arm 5

Intervention name : Licensed Tdap

Intervention Type : Active Comparator

Intervention Classification : Biological/Vaccine

Intervention Description : Tetanus toxoid, diphtheria toxoid and acellular pertussis vaccine, adsorbed (Tdap) given intramuscularly as a single dose (0.5 ml) on day 0

Outcome

Primary Outcome

1. Outcome Name : Percentages of participants with post-immunization local and systemic reactions

Metric / Method of measurement : Self assessment by participant and data record from Diary Card

Time point : During 7 days following vaccination

2. Outcome Name : Percentages of participants with AEs

Metric / Method of measurement : AEs reported by participant

Time point : During 28 days following vaccination

3. Outcome Name : Percentages of participants with SAEs

Metric / Method of measurement : SAEs reported by participant

Time point : From the day of vaccination until Day 28 following vaccination

Secondary Outcome

1. Outcome Name : Seroconversion rates of PT and FHA antibodies in each study vaccine group

Metric / Method of measurement : ELISA

Time point : Day 28 and 1 year after vaccination

2. Outcome Name : Seroconversion rates of tetanus and diphtheria antibodies in BioNet Recombinant Tdap

Metric / Method of measurement : ELISA

Time point : Day 28 and 1 year after vaccination

3. Outcome Name : Seroconversion rates of tetanus and diphtheria antibodies in licensed TdaP

Metric / Method of measurement : ELISA

Time point : Day 28 and 1 year after vaccination

4. Outcome Name : Seroconversion rates of tetanus and diphtheria antibodies in Licensed Tdap (comparator)

Metric / Method of measurement : ELISA

Time point : Day 28 and 1 year after vaccination

5. Outcome Name : GMT antibody concentrations to PT, FHA, tetanus and diphtheria in BioNet Recombinant Tdap

Metric / Method of measurement : ELISA and PT neutralizing assay in CHO cells

Time point : Day 0, 28 and 1 year after vaccination

6. Outcome Name : GMT antibody concentrations to PT, FHA, tetanus and diphtheria in licensed TdaP
Metric / Method of measurement : ELISA and PT neutralizing assay in CHO cells
Time point : Day 0, 28 and 1 year after vaccination
7. Outcome Name : GMT antibody concentrations to PT, FHA, tetanus and diphtheria in licensed Tdap (comparator)
Metric / Method of measurement : ELISA and PT neutralizing assay in CHO cells
Time point : Day 0, 28 and 1 year after vaccination
8. Outcome Name : GMT antibody concentrations to PT, FHA in BioNet Recombinant ap and licensed aP
Metric / Method of measurement : ELISA and PT neutralizing assay in CHO cells
Time point : Day 0, 28 and 1 year after vaccination
9. Outcome Name : Seroconversion rates of PT antibodies in each studies vaccine group
Metric / Method of measurement : PT neutralizing assay in CHO cells
Time point : At day 28 and 1 year after vaccination
10. Outcome Name : Percentages of participants with SAEs
Metric / Method of measurement : SAEs reported by participant
Time point : 1 year after vaccination

Location

Section A : Central Contact

Central Contact	First Name : Vilasinee	Middle Name :	Last Name : Yuwaree
	Degree :	Phone : 023618110 Ext. : 271	Email : vilasinee.y@bionet-asia.com
Central Contact Backup	First Name : Vilasinee	Middle Name :	Lastname : Yuwaree
	Degree :	Phone : 023618110 Ext. : 271	Email : vilasinee.y@bionet-asia.com

Section B Facility Information and Contact

1. Site Name : Division of Infectious Disease Department of Medicine, Faculty of Medicine, Chulalongkorn University

	City : Bangkok	State/Province : Bangkok	Postal Code : 10330
	Country : Thailand	Recruitment Status : Completed	
Facility Contact	First Name : Vilasinee	Middle Name :	Last Name : Yuwaree
	Degree :	Phone : 023618110 Ext. : 271	Email : vilasinee.y@bionet-asia.com
Facility Contact Backup	First Name : Supalak	Middle Name :	Last Name : Yacharoen
	Degree :	Phone : 023618110 Ext. : 271	Email : supalak.y@bionet-asia.com
Investigator Name	First Name : Prof. Teerapong	Middle Name :	Last Name : Tantawichien
	Degree : MD.	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Souad	Middle Name :	Last Name : Mansouri
Degree : PhD.	Phone : 023618110 Ext. : 271	Email : souad.m@bionet-asia.com
Postal Address : BioNet-Asia Co., Ltd. (Branch 1), Hi-Tech Industrial Estate, 81 Moo 1, Baan-Lane, Bang Pa-In		
State/Province : Ayutthaya	Postal Code : 13160	
Country : Thailand	Official Role : Study Director	
Organization Affiliation : BioNet-Asia Co., Ltd.		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Souad	Middle Name :	Last Name : Mansouri
Degree : PhD.	Phone : 023618110 Ext. : 271	Email : souad.m@bionet-asia.com
Postal Address : BioNet-Asia Co., Ltd. (Branch 1), Hi-Tech Industrial Estate, 81 Moo 1, Baan-Lane, Bang Pa-In		
State/Province : Ayutthaya	Postal Code : 13160	
Country : Thailand	Official Role : Study Director	
Organization Affiliation : BioNet-Asia Co., Ltd.		

Summary Results

Date of posting of results summaries : Summary results not yet available
Date of first journal publication of results : Not yet published

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : Undecided

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data