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

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

> Study Start Date (First enrollment): 10 February 2020 Key Trial Dates 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

Allocation: Randomized

Control: Active

Study Endpoint Classification: Safety/Efficacy Study

Masking:

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

 ${\bf 3.\ Outcome\ Name:\ Percentages\ of\ participants\ with\ SAEs}$

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

 $\textbf{2.} \ Outcome \ Name: \ Seroconversion \ rates \ of \ tetanus \ and \ diphtheria \ antibodies \ in \ BioNet \ Recombinant \ Tdap$

Metric / Method of measurement: ELISA

Time point: Day 28 and 1 year after vaccination

 $\textbf{3. Outcome Name: Seroconversion rates of tetanus and diphtheria antibodies in licensed \,TdaP}$

 $Metric \, / \, Method \, of \, measurement: \, \, \, ELISA$

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

 $\begin{tabular}{ll} \textbf{MEDLINE Identifier}: & No\ Data \\ \\ \textbf{URL link to full text publication}: & No\ Data \\ \\ \end{tabular}$