Kinetics of immune responses and characteristics of antigen-specific B cells after Bordetella pertussis vaccination

Published: 21-12-2016
Last updated: 15-04-2024

This study is designed to dissect the immune response after Bp booster vaccination by investigating the kinetics of innate and adaptive immune cells, and detection and characterization of Bp-specific memory B cells and plasma cells.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON52999

Source
ToetsingOnline

Brief title
Immune responses to Bordetella pertussis vaccination

Condition

- Bacterial infectious disorders

Synonym
Pertussis, Whooping cough

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bordetella pertussis, flow cytometry, immune response, vaccination

Outcome measures

Primary outcome

Detailed analysis of innate and adaptive immune cells and their kinetics in time will be performed by the means of flow cytometry. Flow cytometry-based approach will be developed to identify antigen specific memory B cells and plasma cells prior to analysis of their immunoglobulin receptors by the means of high throughput sequencing. Study will be finished while all donors are recruited.

Secondary outcome

Not applicable

Study description

Background summary

Despite obligatory vaccinations against Bordetella pertussis (Bp), the number of Bp infections is gradually increasing world-wide. This phenomenon seems to be caused by the replacement of the whole cellular vaccine (containing whole inactivated bacterium), by the acellular vaccine (containing purified bacteria proteins).To prevent increased Bp infections it is crucial to investigate immune responses to the currently used Bp vaccines and determine biomarkers correlated with prediction of protection, long-lasting memory and early signs of waning.

Study objective

This study is designed to dissect the immune response after Bp booster vaccination by investigating the kinetics of innate and adaptive immune cells, and detection and characterization of Bp-specific memory B cells and plasma cells.

Study design

This is a minimally invasive study, including a booster immunization with a certified vaccine and blood drawing.

Intervention

Volunteers will receive booster vaccination with Boostrix (GSK) after which they will donate blood samples at various fixed time points.

Study burden and risks

Boostrix (GSK) is a vaccine used in a current vaccination scheme in the Netherlands. Additional booster should result in increased immunity against vaccine components, while the risk of severe adverse effects is limited. The main burden for participants will be related to additional venous blood draws following immunization.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy competent adults, who have received recommended vaccinations according to the vaccination policy in the Netherlands

Exclusion criteria

Subjects who meet any of the following criteria will be excluded from participation in this study:
* has an auto-immune disease
* has an immune deficiency
* has a bleeding disorder
* underwent splenectomy
* receives immunosuppressive medication
* receives medication which influences blood clotting
* underwent active (clinically manifested) Bordetella pertussis infection at any time point in life or had contact with such a person
* received Bp vaccination in the past 10 years
* has Hb level below 8.5 mmol/L (male) or below 7.5 mmol/L (female)
* is pregnant or breast feeding
* had an allergic response to vaccination in the past
* received any vaccination within the 14 days prior to the study
* donated blood or plasma within the month prior to the study, or is planning to donate within the first month of the study

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2017
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Boostrix

Ethics review

Approved WMO

Date:	21-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	11-01-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-02-2022

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	09-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2016-002011-18-NL
CCMO	NL57973.058.16

Study results

Date completed:	30-06-2022
Actual enrolment:	20