Transmission and colonisation of pertussis among Dutch high-school adolescents.

Published: 24-03-2020
Last updated: 10-04-2024

This pilot study is designed to evaluate the feasibility of field activities and if necessary adjust the methods for the full-scale study. Primary Objective: to evaluate the recruitment, retention and compliance rates for a prospective cohort study...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON48121

Source
ToetsingOnline

Brief title
Kimi-study

Condition

- Bacterial infectious disorders

Synonym
whooping cough (pertussis)

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Sanofi Pasteur SA.,Sanofi Pasteur SA;Lyon;France

Intervention

Keyword: Bordetella pertussis, immunological biomarkers, transmission., whooping cough

Outcome measures

Primary outcome

In order to evaluate feasibility of the full-scale study as per the primary objective of the pilot study the following endpoints will be collected:

Recruitment rate:

number of index case contacts consenting to participate among the school*s eligible population of index case contacts. In addition, each eligible student who refuses to enrol will be offered to volunteer the reason for refusal.

Retention rate:

number of participants completing the follow-up period among all consenting participants, and duration of follow-up completed for each participant. In addition, each participant who exits the study before end of follow-up will be offered to volunteer a reason for exiting.

Compliance rate: number of follow-up visits and procedures completed by participants who complete the expected follow-up period or less. In addition, participants who miss/refuse follow-up visits and procedures will be offered to volunteer a reason.

Data collection rate:

number of valid results/complete datasets by each participant.

Secondary outcome

- Data collection on participants (e.g. gender, age, vaccination status,

presentation and evolution of clinical symptoms, etc)

- Detection of B. pertussis infection, defined as at least one time point or

multiple consecutive time points with positive PCR

- Immune markers: descriptive analysis of cellular and humoral immune markers

in blood and mucosal lining fluid

Study description

Background summary

Decades after the introduction of whole-cell and acellular pertussis vaccines many countries, including the Netherlands, has seen an increase in pertussis incdience. To develop novel, improved pertussis vaccines, it is essential that immunological biomarkers of protection are identified.

The Dutch healtcare system is well-suited to rapidly and efficiently detect local outbreaks of pertussis. As a consequence of the relatively recent introduction of acellular pertussis vaccines (in 2005), Dutch high-school adolescents comprise a mixed population of individuals who were either vaccinated during infancy with the 'old' whole-cell or with the 'new' acellular pertussis vaccines. To identify immunological biomarkers of protection, we want to initiate an epidemiological investigation of pertussis transmission and colonisation amongst high-school students and their immune markers. Before a larger, full-scale study can be started, the current protocol has been designed as a pilot study.

Study objective

This pilot study is designed to evaluate the feasibility of field activities and if necessary adjust the methods for the full-scale study.

Primary Objective:
to evaluate the recruitment, retention and compliance rates for a prospective cohort study, and to assess the feasibility of sampling procedures, frequency and information collection for the aim of optimizing the proposed full-scale study.

Secondary Objective(s):
to descriptively analyse study outcomes (colonization, disease and immune markers) to support powering analyses of full-scale study

Study design

This is a community-based, monocenter, prospective observational cohort pilot study with invasive procedures.

Study burden and risks

Holding an arm when taking a blood sample may feel uncomfortable and the puncture of the needle may be a bit painful and a bruise may occur. If desired an anesthetic cream/spray/plaster will be used so that the puncture will hardly be felt. The collection of nasal fluid can cause sneezing and watery eyes. This is of a temporary nature and there are no major risks associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For index case (= patient):
• Laboratory-confirmed pertussis
• Attending any grade in a pre-trade (grades 1-4) or standard (grades 1-5 or 1-6) high-school in Gelderland, Utrecht, Overijssel, Noord-Brabant
• At least 12 years of age

For contacts (= healthy subject) :
• Be one of at least 8 contacts among the cluster of consenting contacts in the same school as the index case
• At least 12 years of age
• No recorded diagnosis of pertussis prior to study start
• Regular daily attendance to the same school as index case over the study period.

Exclusion criteria

Participants with contact with any individual of increased risk in their immediate surroundings as defined by the national guidelines (https://lci.rivm.nl/richtlijnen/kinkhoest).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	113
Type:	Anticipated

Ethics review

Approved WMO Date:	24-03-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-10-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL72245.091.19

Register	ID
Other	Wordt geregistreerd bij clinicaltrials.gov