Third population-based immune surveillance study for the evaluation of the National Immunisation Programme in the Netherlands: the PIENTER3 study

Published: 07-10-2015
Last updated: 20-04-2024

To obtain insight into the age-specific seroprevalence (immunity) for diseases included in the NIP of the Dutch general population.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON42468

Source
ToetsingOnline

Brief title
PIENTER3

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
immune system, protection against infectious diseases

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: immunity, infectious diseases, National Immunisation Programme, surveillance

Outcome measures

Primary outcome

The age-specific seroprevalence (immunity) for diseases included in the NIP of

the Dutch general population.

Secondary outcome

The age-specific seroprevalence against other infectious diseases, in

particular those that might be vaccine-preventable in the near future and

against those diseases with a frequent subclinical course.

By collecting additional samples, the relationship between immune status and

carriage of potential pathogens, lifestyle factors and environmental factors

can be studied.

Study description

Background summary

Measuring the serological effects of the different vaccinations (immune surveillance) is an important tool for the evaluation of the National Immunisation Programme (NIP) by providing insight in the immune status of the population, by identifying possible gaps in the immunity and subpopulations at risk and by assessing (re) emergence of disease.

Study objective

To obtain insight into the age-specific seroprevalence (immunity) for diseases included in the NIP of the Dutch general population.

Study design

This study is an observational study with a single invasive measurement

(drawing of blood) and non-invasive measurement (saliva). For a subgroup, optional, a nose and throat swab will be collected as well as a faecal sample.

Study burden and risks

Discomfort from blood collection is present and is considered a minimal burden. If invitee agrees to participate in the optional additional investigations there will be discomfort for a short duration during the swabs of the nose and throat. The study is a cross-sectional study and aims to be representative of the Dutch population. The primary endpoint is the evaluation of the NIP. Therefore the age groups under 5 years are of special interest and cannot be excluded from this study. The questionnaire contains several questions about health perception, diseases and vaccination data but also some more personal questions regarding sexual behaviour and sexual transmitted diseases are asked. The participant is free to answer or to skip these personal questions.

Contacts

Public
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL
Scientific
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

* Subject is part of the study sample, aged 0 to 89 years old and has received a personal invitation for the PIENTER3 study.
* Subject has given written Informed Consent (IC) before the start of the study visit.

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2016
Enrollment:	8400
Type:	Actual

Ethics review

Approved WMO

Date:	07-10-2015

Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	04-11-2015
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	13-04-2016
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	24-05-2016
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	29-08-2016
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	17-11-2016
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL54228.094.15