PIENTER-onderzoek

No registrations found.

| Ethical review | Positive opinion |
|-----------------------|----------------------------|
| Status | Pending |
| Health condition type | - |
| Study type | Observational non invasive |

Summary

ID

NL-OMON24544

Source NTR

Brief title PIENTER3

Health condition

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

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM) **Source(s) of monetary or material Support:** Ministry of Health, Welfare and Sports (VWS)

Intervention

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. To obtain insight into the age-specific seroprevalence (immunity) for diseases included in the NIP of the Dutch general population, this observational study with a single invasive measurement (drawing of blood) and non-invasive measurement (saliva) is performed. For a subgroup, optional, a nose and throat swab will be collected as well as a faecal sample. A representative part sample of the Dutch population (age 0-89 years) is invited to participate. The age-specific seroprevalence (immunity) for diseases included in the NIP of the Dutch general population and 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, will be asessed.

Study objective

Rationale: 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 design

A single time point for the collection of samples.

Intervention

None

Contacts

Public Antonie van Leeuwenhoeklaan 9-11 R.A.J. Boxtel, van Bilthoven 3721 MA The Netherlands +31 (0)30 2742755 Scientific Antonie van Leeuwenhoeklaan 9-11 R.A.J. Boxtel, van Bilthoven 3721 MA The Netherlands +31 (0)30 2742755

Eligibility criteria

Inclusion criteria

• Subject is part of the national study sample drawn from the population register, aged 0 to 89 year old and has received a personal invitation for the PIENTER study.

• Subject has given written Informed Consent (IC) before the start of the study visit.

Exclusion criteria

None

Study design

Design

Study type: Intervention model: **Control:** N/A , unknown Observational non invasive Other

Recruitment

| NL | |
|---------------------------|-------------|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2016 |
| Enrollment: | 8400 |
| Туре: | Anticipated |

Ethics review

| Positive opinion | |
|-------------------|------------------|
| Date: | 05-01-2016 |
| Application type: | First submission |

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 |
|----------|--------------------------|
| NTR-new | NL5467 |
| NTR-old | NTR5611 |
| Other | NL54228.094.15 : IIV-284 |

Study results

Summary results

Van der Klis FR, Mollema L, Berbers GA, de Melker HE, Coutinho RA. Second national serum

bank for population-based seroprevalence studies in the Netherlands. Neth J Med. 2009 Jul-Aug;67(7):301-8.

Mollema L, de Melker HE, Hahné SJM, van Weert JWM, Berbers GAM, van der Klis FRM. PIENTER 2 project: second research project on the protection against infectious diseases offered by the national immunization programme in the Netherlands. RIVM report 230421001/2009.

PIENTER2 study 2006-2007: A summary of the main findings. Van der Klis FRM, Mollema L, van Weert JWM. RIVM report, April 2012.