

# Second serosurveillance study in The Netherlands for the evaluation of the Dutch National Immunisation Programme: the PIENTER 2 study

<b>Submission date</b> 27/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/03/2013	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.pienterproject.nl>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

**Scientific Title**

**Acronym**

PIENTER 2

**Study objectives**

The age-specific seroprevalence of a cross-section of the Dutch population for the vaccinations used in the Dutch National Immunisation Programme.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received from the local ethics committee (Stichting Therapeutische Evaluatie Geneesmiddelen [STEG]) on the 11th October 2005 (ref: R05-044).

**Study design**

Observational, cross-section survey

**Primary study design**

Observational

**Secondary study design**

Cross-section survey

**Study setting(s)**

Not specified

**Study type(s)**

Screening

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Vaccination and the National Immunisation Program, infectious diseases

**Interventions**

A blood sample and a questionnaire regarding health perception, diseases (including sexually transmitted), vaccination data.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

The age-specific seroprevalence (immunity) for diseases included in the National Immunisation Program of the Dutch general population.

As each participant is sampled only once, there will be only one timepoint measurement per person. The timepoint for the complete study population varies from February 2006 to June 2007. Because the participants represent a cross section of the Dutch population aged 0 to 80, we will be able to estimate the seroprevalence in the Dutch population in 2006-2007.

**Secondary outcome measures**

1. 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
2. The age-specific seroprevalence amongst the allochtonous populations (additional sample)
3. The age-specific seroprevalence amongst non-vaccinated orthodox reformed individuals (additional sample)

As each participant is sampled only once, there will be only one timepoint measurement per person. The timepoint for the complete study population varies from February 2006 to June 2007. Because the participants represent a cross section of the Dutch population aged 0 to 80, we will be able to estimate the seroprevalence in the Dutch population in 2006-2007.

**Overall study start date**

06/02/2006

**Completion date**

19/06/2007

**Eligibility****Key inclusion criteria**

1. Subject is part of the study sample
2. Aged 0 - 79 years old
3. Has received a personal invitation for the study
4. Subject has given written informed consent before start of the study

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

7700

**Key exclusion criteria**

Subject is an employee of the National Institute of Public Health and Environmental Protection (RIVM).

**Date of first enrolment**

06/02/2006

**Date of final enrolment**

19/06/2007

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**National Institute of Public Health and Environmental Protection (RIVM)**

Bilthoven

Netherlands

3720 BA

## **Sponsor information**

**Organisation**

National Institute of Public Health and Environmental Protection (RIVM) (The Netherlands)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.rivm.nl/en/>

**ROR**

<https://ror.org/01cesdt21>

# Funder(s)

## Funder type

Government

## Funder Name

The Netherlands Ministry of Health, Welfare and Sport (The Netherlands)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	19/10/2012		Yes	No
<a href="#">Results article</a>	results	01/04/2014		Yes	No