Pre-Study Carriage in Elderly (No. 6115A1-3014)

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Determine asymptomatic nasopharyngeal pneumococcal carriage and serotype distribution in elderly aged 65-70 years, 71-80 years ald 80 years and older. Assessment of the value of PCR compared with conventional culture methods.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30857

Source
ToetsingOnline

Brief title
Pneumococcal carriage study

Condition

- Bacterial infectious disorders

Synonym
pneumococcal carriage prevalence

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Wyeth (pharmaceutisch bedrijf)

Intervention

Keyword: Elderly > 65 year of age, nasopharyngeal pneumococcal colonisation, serotype distribution

Outcome measures

Primary outcome

Pneumococcal carriage rates will be determined in at least 100 elderly per age

category (aged 65-70 years, 71-79 years and 80 years and older).

Rates of pneumococcal nasopharyngeal carriage by conventional culture methods

and Polymerase Chain Reaction (PCR) will be compared.

Secondary outcome

Influence of exposure to other people (particularly children) will be explored

via questionnaires.

Study description

Background summary

Respiratory and invasive pneumococal infections are an important cause of morbidity and mortality among elderly, particularly pneumonia. With age, the contribution of the pediatric serotypes increases. However, data on asymptomatic nasopharyngeal carriage prevalence and serotype distribution in elderly are scarce. The value of PCR analysis may enhance sensitivity compared with conventional culture methods.

Study objective

Determine asymptomatic nasopharyngeal pneumococcal carriage and serotype distribution in elderly aged 65-70 years, 71-80 years ald 80 years and older. Assessment of the value of PCR compared with conventional culture methods.

Study design

Elderly of 65 years and older who are eligible for the annual influneza vaccination, will be selected for the carriage prevalence study by the GP and

invited to participate via the primary care physician.

The study subjects will visited at home once for the collection of 2 transnasal and 2 transoral swabs. A questionnaire by the research nurse or physiocian will collect data on related to risk factors for pneumococcal carriage (health, environment, life style and contacts with young children).

The study outcome will be descriptive. To detect at least 7% carriage with 90% power and alfa of 5% , 300 elderly persons are needed. A drop out rate of 10% is expected; therefore 110 subjects per age group will be included in order to have 100 evaluable subjects per age group.

The project is a collaboration of the Wilhelmina Children*s Hospital and the Julius Center of the UMC Utrecht together with the Spaarne Hospital in Hoofddorp and the GPs in the Hoofddorp/Nieuw Vennep region.

Study burden and risks

One home visit of approximately 45 minutes. The risk of non-severe and self limiting nose bleeding is less tha 1:1000 (according to studies in infants)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Persons aged 65 years and older
2. Obtained written informed consent

Exclusion criteria

1. Persons in healthcare institutions or nursing homes (in The Netherlands these persons are not listed at the GP practice);
2. Patients who can not fulfil study procedures according to the GP;
3. The use of experimental trial medication within 30 days preceding the pre-study;
4. The use of antibiotics within 30 days preceding the pre-study;

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2007
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL18519.041.07