Vaststellen van ziekteverwekkers van griepachtige verschijnselen en karakteriseren van de afweerrespons bij ouderen in Nederland

No registrations found.

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

Summary

ID

NL-OMON26253

Source
Nationaal Trial Register

Brief title
GRIEP-3

Health condition

Infectious diseases, Influenza, Viral, Bacterial, Carriage

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Primary: to determine the percentage of ILI attributable to influenza virus in elderly

individuals > 60 years of age

Secondary outcome

Secondary: to determine the relative contribution of influenza viral subtypes

Secondary: to determine humoral and cellular immune responses to influenza virus

Secondary: to identify which microorganisms (viral and bacterial) present in nasopharynx and oropharynx of elderly suffering from ILI are potential other causes for ILI

Secondary: to determine humoral and cellular immune responses towards the potential pathogens identified in PCR/culture data

Secondary: to gain insight in the influence of viral presence on co-colonization of well-known respiratory bacteria like S. pneumoniae, H. influenzae, M. catarrhalis, S. aureus in elderly by comparing colonization during ILI, after recovery and without having had ILI (baseline)

Secondary: to compare the presence of S. pneumoniae in nasopharyngeal swab with saliva

Exploratory: to evaluate whether differences can be found in incidence of influenza virus infection between subjects who have, and those who have not, received the seasonal influenza vaccine in the year of study

Exploratory: to compare the incidences of the detected pathogens with other available age group cohorts or with other cohorts of the same age group, such as the previous GRIEP-1/-2 study

Exploratory: to evaluate the immune responses to different herpesviruses in the context of a possible role in immunosenescence

Exploratory: to analyze the intestinal microbiome in context of influenza vaccination response and identified microorganisms

Exploratory: to evaluate whether there is a difference in the general physical and mental health condition as assessed by SF-36 questionnaire and vaccine acceptance between the subjects that report with ILI and the whole study population

Study description

Background summary

The public is questioning the effectiveness of seasonal influenza vaccination in elderly as a result of the general impression that all influenza-like illness (ILI) is caused by an influenza

virus infection. However, several pathogens, both viral and bacterial, can cause ILI. A better understanding of the percentage of ILI caused by an influenza virus infection and the contribution of other respiratory viruses or involvement of bacteria will allow a better appreciation of seasonal influenza vaccines. In addition, information will be collected on the humoral and cellular immune responses induced by the different viruses, bacteria and influenza vaccination, the severity of respiratory symptoms during ILI, respiratory symptoms in the absence of ILI, the acceptance of influenza vaccination and the influence of the intestinal microbiome on the immune responses after infection or vaccination.
Elderly either community-dwelling or living in nursing homes will be included.

Study objective

The general public is questioning the effectiveness of seasonal influenza vaccination in elderly as a result of the general impression that all influenza-like illness (ILI) is caused by an influenza virus infection. However, several pathogens, both
viral and bacterial, can cause ILI. A better understanding of the percentage of ILI caused by an influenza virus infection
and the contribution of other respiratory viruses or involvement of bacteria will allow a better appreciation of seasonal influenza vaccines. The immune response against identied pathogens will be further characterized.

Study design

Timepoint 1: Within 72 hours after onset of fever and at least 1 other ILI symptom;

Timepoint 2: 2-3 weeks after timepoint 1;

Timepoint 3: 7-9 weeks after timepoint 1;

Extra timepoint 1: Any timepoint in subjects who do not (yet) have ILI symptoms during the influenza season and a repeat timepoint 2-3 weeks after extra timepoint 1.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. 60 years of age and older;

2. Willing to present when influenza-like-illness (ILI) symptoms occur;

3. Signed Informed Consent.

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2014

Enrollment:	4000
Type:	Anticipated

Ethics review

Positive opinion
Date: 30-09-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40776
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4666
NTR-old	NTR4818
CCMO	NL49128.094.14
OMON	NL-OMON40776

Study results