Identification of potential pathogens responsible for influenza-like illness in elderly in The Netherlands. Evaluation of humoral and cellular immunity against identified microorganisms

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Primary: to determine the percentage of ILI attributable to influenza virus in elderly individuals * 60 years of age Secondary: to determine the relative contribution of influenza viral subtypesSecondary: to determine humoral and cellular immune...

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

Summary

ID

NL-OMON40776

Source
ToetsingOnline

Brief title
ILI in elderly - GRIEP-3

Condition

- Viral infectious disorders

Synonym
flu, influenza

Research involving
Human

Sponsors and support

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

Intervention

Keyword: elderly, humoral and cellular immunity, Influenza-Like-Illness (ILI), respiratory pathogens

Outcome measures

Primary outcome

Primary: presence of influenza virus in nasopharyngeal and oropharyngeal swab

during ILI episodes

Secondary outcome

Secondary: influenza virus subtypes in case of influenza infection

Secondary: antibody levels to influenza virus and activation of T cells after

influenza infection (humoral and cellular immune responses)

Secondary: presence of viruses (other than influenza) in nasopharyngeal and

oropharyngeal swabs collected in subjects reporting with ILI during ILI

episodes, 2-3 weeks later and 7-9 weeks later, and additionally at two time

points with a 2-3 week interval in a subset of participants without having had

ILI

Secondary: presence of bacterial microorganisms in nasopharyngeal and

oropharyngeal swabs collected in subjects reporting with ILI during ILI

episodes, 2-3 weeks later and 7-9 weeks later after, and additionally at two

time points with an interval of 2-3 weeks in a subset of participants without

having had ILI

Secondary: humoral and cellular immune responses against potential pathogens

identified in PCR/culture data

Secondary: presence of S. pneumoniae in saliva

Secondary: a SF-36 (short-form health survey) questionnaire and vaccine

acceptance at the start of the season, i.e. after signing of Informed Consent

Exploratory: humoral and cellular immune responses against herpes viruses

Exploratory: profile of the intestinal microbiome

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 also 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 earlier studies in this population, the incidences of influenza and other microorganisms were determined in subjects with ILI, in seasons of varying influenza incidence, including the humoral response.
In the follow-up study additional information will be collected on the 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.

Study objective

Primary: to determine the percentage of ILI attributable to influenza virus in elderly individuals * 60 years of age
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 design

Observational cross-sectional study without an investigational medicinal product but with invasive measurements.

Study burden and risks

The burden associated with participation are reporting of ILI, and collection of a nasopharyngeal swab, an oropharyngeal swab, 6 tubes of blood (53 ml), some saliva and a small faecal sample in case a subject reports with ILI. This sample collection is repeated twice. We expect that at least 200 subjects will report with ILI during the season. In a subset of 150 subjects who have not (yet) experienced ILI the same sample sets are collected twice.
The potential risks are considered minimal. There are no benefits for the individual subjects who participate in this trial. The results may contribute to a better control of respiratory diseases on a population level in the future. The study population is the target of the yearly influenza vaccination campaign.

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

* * 60 years of age
* Willing to present when ILI symptoms occur
* Signed Informed Consent

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2014
Enrollment:	2500
Type:	Actual

Ethics review

Approved WMO Date:	04-07-2014
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	22-09-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	24-12-2014
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

ID: 26253
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49128.094.14
OMON	NL-OMON26253