Identification of pathogens responsible for influenza-like illness in elderly in The Netherlands

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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 immune response to...

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

Summary

ID

NL-OMON36114

Source
ToetsingOnline

Brief title
ILI in elderly

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, identification pathogens, Influenza-like illness (ILI)

Outcome measures

Primary outcome

Primary: presence of influenza A and B virus in nasal swab during ILI episodes

Secondary outcome

Secondary: subtyping of influenza viruses in case of influenza infection

Secondary: antibody levels to influenza virus

Secondary: presence of viral (other than influenza A or B) and bacterial microorganisms in nasal and transoral nasopharyngeal swabs respectively after reporting of ILI by the participants during ILI episodes and 8 weeks later. The following micro-organisms will at least be screened by PCR or conventional bacterial culture: human parainfluenza virus, RSV A and B, adenovirus, coronavirus, hMPV, human rhinovirus, bocavirus and polyomaviruses, Mycoplasma pneumoniae, S. pneumoniae, H. influenzae,M. catarrhalis, S. aureus,, N. meningitidis and B. pertussis. Other pathogens might be added if diagnosis is still inconclusive or if other pathogens become prevalent during this season. Additional pneumococcal serotyping may be performed by multiserotype PCR.

Secondary: presence of S. pneumoniae in saliva

Secondary: antibody levels towards viral and bacterial pathogens present in the swabs as identified by PCR or bacterial culture.

Secondary: a SF-36 (short-form health survey) questionnaire at baseline.

Study description

Background summary

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. In addition, information will be collected on the occurrence of viral and bacterial co-infections.

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 immune response to influenza virus
Secondary: to identify which microorganisms (viral and bacterial) present in nose and nasopharynx of elderly suffering from ILI are potential other causes for ILI
Secondary: to determine humoral immune response towards the potential pathogens based on culture/PCR data
Secondary: to gain insight in the influence of viral presence on co-colonization of well-known respiratory bacterial pathogens like S. pneumoniae, H. influenza, M. catarrhalis, S. aureus in elderly by comparing colonization during ILI and after recovery.
Secondary: to compare detection of pneumococcal detection in nasopharyngeal swabs with saliva
Exploratory: to evaluate whether differences can be found in incidence of influenza virus detection between subjects who have received the seasonal influenza vaccine 2011-2012 or who did not receive the seasonal influenza vaccine 2011-2012.
Exploratory: to evaluate whether there is a difference in the general physical and mental health condition as assessed by SF-36 questionnaire 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 nasal swab and a transoral nasopharyngeal swab, and 1 tube of blood (10 ml) in case of ILI symptoms. This will be repeated 8 weeks later. The potential risks are considered minimal. There are no benefits for the individual subjects who participate in this trial. The results are possibly of benefit 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):	10-11-2011
Enrollment:	2100
Type:	Actual

Ethics review

Approved WMO Date:	18-10-2011
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	16-12-2011
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

No registrations found.

In other registers

Register	ID
CCMO	NL37392.094.11