Vaststellen van ziekteverwekkers van griepachtige verschijnselen bij ouderen.

No registrations found.

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

Summary

ID

NL-OMON22474

Source
Nationaal Trial Register

Brief title
GRIEP-1, GRIEP-2

Health condition

infectious diseases, influenza, viral and bacterial co-infections, carriage
(in Dutch: infectieziekten, griep, virale en bacteriele infecties, dragerschap)

Sponsors and support

Primary sponsor: Rijksinstituut voor Volksgezondheid en Milieu (RIVM)
Source(s) of monetary or material Support: Ministry of Health, Welfare and Sport (VWS)

Intervention

Outcome measures

Primary outcome

Presence of influenza A and B virus in nasal swab during ILI episodes.

Secondary outcome

1. Subtyping of influenza viruses in case of influenza infection;

2. Antibody levels to influenza virus;

3. 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;

4. Presence of S. pneumoniae in saliva;

5. Antibody levels towards viral and bacterial pathogens present in the swabs as identified by PCR or bacterial culture;

6. 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

Influenza-like-illness (ILI) is not only caused by an influenza virus infection, but also by other pathogens, both viral and bacterial. In this study nose and throat swab samples will be taken during ILI episodes to identify pathogens causing ILI in the elderly population.

Study design

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

Timepoint 2: 8 weeks after timepoint 1;

Extra timepoint: Any timepoint in subjects who do not (yet) have ILI symptoms during the influenza season.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. ≥ 60 years of age;

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

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2011
Enrollment:	2500
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-04-2012
Application type:	First submission

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
NTR-new	NL3234
NTR-old	NTR3386
Other	ABR / protocol ID : 37392 / VAC-261;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A