Monitoring of influenza-like symptoms among elderly, an observational study

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Primary Objective: • To determine the incidence rate of self-reported ILI.Secondary Objectives: • To determine the efficacy of 13vPnC in preventing a first episode of self-reported LRTI.• To explore the effect of 13vPnC on the incidence of self-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON34406

Source
ToetsingOnline

Brief title
Monitoring of ILI symptoms among elderly, an observational study

Condition

- Respiratory tract infections

Synonym
influenza-like illness, respiratory tract infections

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Pfizer,sponsoring (investigator initiated research) aangevraagd bij Pfizer Inc.

Intervention

Keyword: influenza-like illness, lower respiratory tract infection, pneumococcal vaccination, self-reported

Outcome measures

Primary outcome

incidence of a first episode of self-reported ILI

Secondary outcome

1. incidence of self-reported LRTI

2. proportion of episodes requiring visit to general practitioner

Study description

Background summary

Influenza, influenza-like illness (ILI) and lower respiratory tract infections (LRTI) are common and represent a major healthcare problem worldwide. Influenza facilitates secondary bacterial infection, of the respiratory tract, frequently by Streptococcus pneumoniae resulting in high hospitalisation and mortality rates, especially in elderly patients.
Since the winter season of 2003/2004 incidence and prevalence of ILI have been successfully measured in the Netherlands using an internet-based surveillance system, highly sensitive to short-term changes and producing incidence figures comparable to regular influenza surveillance by a sentinel network of GPs, however, elderly are clearly underrepresented in the internet-based system.
The CAPITA-trial is a placebo-controlled double-blind randomized trial to determine the efficacy of a new 13-valent pneumococcal conjugate vaccine (13vPnC) in preventing hospitalization due to pneumococcal CAP. As of now, no information on respiratory infections is collected outside the hospital setting.
In this observational study nested within the CAPiTA trial we aim to quantify the incidence and burden of self-reported ILI and LRTI in the elderly CAPiTA population, and in addition establish the effect of pneumococcal vaccination hereon, by using a weekly internet-based questionnaire. Our methodology is comparable to the previously used web-based influenza surveillance.

Study objective

Primary Objective:
• To determine the incidence rate of self-reported ILI.
Secondary Objectives:
• To determine the efficacy of 13vPnC in preventing a first episode of self-reported LRTI.
• To explore the effect of 13vPnC on the incidence of self-reported ILI.
• To determine the incidence of self-reported LRTI symptoms among CAPiTA participants.
• To determine the proportions of self-reported LRTI episodes for which GPs are consulted.
• To determine self-reported ILI and self-reported LRTI incidence rates in different age- and comorbidity-groups.

Study design

This is an observational study nested within a placebo-controlled double-blind randomized trial (CAPITA-trial).

Intervention

During this study no intervention will take place. Participants of this study also participate in the CAPiTA trial, a double-blind vaccination trial during which they received either a 13-valent pneumococcal conjugate vaccine or placebo.

Study burden and risks

Subjects will be asked to report whether they have experienced ILI- and/or LRTI-symptoms on a weekly basis from October 2010 till April 2011, through a web-based questionnaire. No investigational medicinal product will be administered during the present study, and the execution of the CAPiTA trial will not be influenced.

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. participation in the CAPiTA study
2. able to fill in an internet-based questionnaire

Exclusion criteria

1. lost to follow-up or withdrawn from the CAPiTA study
2. Residence in a nursing home, long-term care facility or other institution, or requirement of semiskilled nursing care

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2010
Enrollment:	11000
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Prevenar 13

Ethics review

Approved WMO Date:	02-09-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-10-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2010-022682-98-NL
CCMO	NL33774.000.10