Clinical course and burden of disease of lower respiratory tract infections in primary care

Published: 17-12-2010
Last updated: 04-05-2024

1. To evaluate the burden of disease of CAP and other LRTI in elderly in primary care in terms of duration of symptoms, number of hospitalization and mortality, and number of complications.2. To evaluate the burden of disease of CAP and other LRTI...

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

Summary

ID

NL-OMON36564

Source
ToetsingOnline

Brief title
Burden of disease of LRTI in general Practice

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
lower respiratory tract infections, pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Pfizer,Pfizer Inc

Intervention

Keyword: burden, lower respiratory tract infection, pneumonia, primary care

Outcome measures

Primary outcome

Primary endpoint: duration of symptoms of CAP and other LRTI.

Secondary outcome

Secondary endpoints: complications of CAP and other LRTI, quality of life and daily activities, number of infections with Streptococcus pneumoniae, number of infections with other bacterial pathogens (Haemophilus influenzae, Moraxella catharralis, Mycoplasma pneumoniae).

Study description

Background summary

Respiratory tract infections are among the most common reasons for patients to visit the GP practice. Lower respiratory tract infections (LRTI) are seen most often in elderly and increase with age. Pneumonia is associated with a worse outcome in older adults, which is reflected by high complication or hospitalization rates and mortality figures. In addition to severe complications, comorbid disorders and quality of health and daily activity level can also temporarily be impaired by LRTI, as is demonstrated in hospital based studies. Only very few data are available on duration of symptoms of LRTI and its effects on comorbidity and quality of life and daily activities among elderly in primary care. It is also unknown to what extent co-morbidity including underlying chronic lung disease does modify the course of lower respiratory tract infections and related burden of disease.
Streptococcus pneumoniae is the most frequent causative pathogen found in CAP but exact figures on bacterial frequencies are currently lacking.
With this study we aim to provide insight into the burden of LRTI in the primary care setting, in terms of duration of symptoms, number of complications and health related quality of life. In addition, we aim to determine the proportion of bacterial and in specific pneumococcal infections of total LRTI in primary care.

Study objective

1. To evaluate the burden of disease of CAP and other LRTI in elderly in primary care in terms of duration of symptoms, number of hospitalization and mortality, and number of complications.
2. To evaluate the burden of disease of CAP and other LRTI in elderly in primary care in terms of daily activities and health-related quality of life.
3. To study the relation between co-morbidity and burden of disease
4. To evaluate the frequency of Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catharralis and Mycoplasma pneumoniae in elderly in primary care presenting with a LRTI.

Study design

prospective observational study

Study burden and risks

After subjects have given informed consent, the GP or a research physician will collect data on symptoms, medical history and comorbidity. In addition a blood sample, a urine sample, an oropharyngeal swab and if possible a sputum sample will be collected at the GP practice, local laboratory or at the subject*s home. Severity of infection will be assessed using the following parameters : respiratory frequency, heart rate, blood pressure, fever, C-reactive protein and the clinical diagnosis according to GP diagnosis code and specific definitions. A sub-analysis of CAP-cases will be made based on the GP*s clinical diagnosis (ICPC code R81: pneumonia) with the presence of at least 3 signs/symptoms suggestive for pneumonia. Presence of Streptococcus pneumoniae will be assessed using the Binax urinary antigen test. Presence of bacterial pathogens will be assessed with one nasopharyngeal and one oropharyngeal swab for PCR-testing and/or sputum culture. Subjects will be asked on day 1 to fill in a diary on their symptoms and any need for seeking medical assistance for the duration of their complaints with a maximum of 4 weeks, On day 1 and then every week up to 4 weeks subjects fill in a health instrument (EQ-5D) to assess quality of life and daily activity levels. After 3 months subjects will be asked to fill in the EQ-5D instrument one more time. Data on hospitalization, death, and any unscheduled visits to the GP practice or outpatient department or emergency department of a hospital within 28 days of the start of the LRTI episode will be collected retrospectively in the subject*s medical file in the GP practice.
The extra time during consultation in the GP practice will be 5 minutes. The laboratory home visit will take 10 minutes. A risk of drawing blood is development of local haematoma which will resolve in a few days. Filling in the diary will take 2 minutes per day and filling in the questionnaires will take 2 minutes per questionnaire.

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.Male or female adults aged 50 years or older
2.Registered with a GP who is participating in the study
3.an acute cough lasting for at least 3 days
4.Symptoms/signs suggestive of CAP or other LRTI (see protocol section 2: Definitions)
5.able to fill in a diary

Exclusion criteria

1.Residence in a nursing home, long-term care facility or other institution, with requirement of semiskilled nursing care.
2.Immune deficiency or suppression, defined as presence of immunocompromising disease or

chronic use of immunosuppressive drugs (for prednisone low doses are allowed).
3. Hospitalisation within 7 days preceding date of inclusion
4. Severity of illness requiring hospitalisation on date of inclusion
5. Use of systemic antibiotic drugs within 14 days preceding date of inclusion
See protocol paragraph 5.3 Exclusion criteria

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2010
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	20-09-2011
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-11-2011
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	29-11-2011
Application type:	Amendment
Review commission:	METC NedMec

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	NL34289.041.10