Transition of medical care: Cough patient outcome by a nurse practitioner.

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To investigate whether cough measurements by means of VAS (0-100 points) after 6 months (+/- 6 points) in patients with chronic cough who are diagnosed and treated by a nurse practitioner outpatient clinic are equal to an outpatient clinic leaded by...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON30376

Source
ToetsingOnline

Brief title
Cough outpatient clinic by nurse.

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
chronic cough; cough > 8 weeks.

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: maatschap longziekten.

Intervention

Keyword: cough outpatient clinic, nurse

Outcome measures

Primary outcome

1. the difference in cough after 6 months in patients with a chronic cough between the cough outpatient clinic of the pulmonologist and nurse practitioner.

Secondary outcome

1. the difference in cough scores after 6 months between both groups for LCQ.

2. the difference in HADS scores after 6 months for both groups.

3. the diagnosis of the nurse practitioner vs the pulmonologist.

4. the number and sort of investigations to obtain a diagnosis.

4. the number of patients after 6 months with an increase / decrease of their complaints (global rating of change questionnaires).

5. patient satisfaction after 6 months.

Study description

Background summary

Chronic cough; cough > 8 weeks is a frequently seen problem. Prevalention is estimated at 20 % and 10 % of the patients is referred to a cough outpatient clinic with this problem. Three mechanisms are responsible for this phenomenon in 90% of the cases; asthma, upper tract infection and reflux. This as an explanation why therapy of chronic cough is so difficult.

In the US and Engeland special cough outpatient clinics with an anatomic-diagnostic protocol seem to be very effective. In 2004 a cough

outpatient clinic is started in the Isala klinieken in the Netherlands. Since 2004, 600 patients are analysed via this outpatient clinic.

Since the diagnostic and therapeutic program is protocolised, it should be possible to transition medical care from pulmonologist to nurse practitioner. An advantage could be that a nurse practitioner is better able to work throughout the different specialisms.

Study objective

To investigate whether cough measurements by means of VAS (0-100 points) after 6 months (+/- 6 points) in patients with chronic cough who are diagnosed and treated by a nurse practitioner outpatient clinic are equal to an outpatient clinic leaded by a pulmonologist.

Study design

Design: prospective randomised single centre trial.

Threehundredandten patients are referred to the cough outpatient clinic from the primary medical line (GP) with chronic cough (existing >8 weeks) without a certain diagnosis. Patients will be asked for participation by informed consent. Inclusion will be during three years and will last 6 months for every patient.

Exclusion criteria are chronic cough in medical history, analyzed and/or treated by a pulmonologist, gastro-enterologist or an ear-nose and throat specialist
and co-morbidity limiting decision making.

Participating patients will be randomised for age and gender by a computer minimisation program for both groups; cough outpatient clinic by pulmonolgist or nurse practitioner (experimental group). Patients in both groups will be analyzed by the same anatomic-diagnostic protocol.

During the first visit questionnaires will be filled in by participating patients:

- Illness specific quality of life by the dutch version of the Leicester Cough
Questionnaire.

-The dutch version of the Hospital Anxiety and Depression Scale (HADS).

- the degree of cough in the last 24 hours by means of the Visual Analogue Scale.

- Baseline characteristics will be noted.

Follow-up

In the first week of every month the VAS will be detected during 6 months, whereby the average score will be calculated for every week (7 times).The HADS and LCQ will be performed at the beginning and after 3 and 6 months. Also a Global Rating of Change questionnaire (GRC) and a patient satisfaction questionnaire will be filled in after 6 months.

With the medical dossier of the participating patients it will be find out which diagnosis is obtained and which diagnostic approaches were needed.

Study burden and risks

There are no (additional) risks due to participation. The burden are the questionnaires; twice the LCQ,HADS,VAS and once patient satisfaction questionnaire and the GRC questionnaire. An advantage could be that a nurse practitioner is better able to work throughout the different specialisms.

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. patients >= 18 years.
2. cough > 8 weeks
3. referred via general practitioner.

Exclusion criteria

1. chronic cough in medical history, treated by a pulmonologist, gastro-enterologist or ear-nose and throat specialist.
2. co-morbidity limiting decision making.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-10-2007
Enrollment:	310
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2006
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL14700.075.06