Does an easy device help doctors to diagnose COPD.

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Microspirometry result in a higher proportion of diagnostic spirometric assessment to objectify the existence or absence of a chronic airflow obstruction within 3 months after a patients at risk for COPD visited the GP compared to usual care.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20427

Bron
NTR

Verkorte titel
EMPERIC

Aandoening

COPD
diagnostic procedure

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Department of primary and community care
Overige ondersteuning: Boehringer Ingelheim

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion of diagnostic spirometric assessment to objectify the existence or absence of a chronic airflow obstruction within 3 months after a patients at risk for COPD visited the GP.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: FEV1/FEV6 ratio assessment in a GP's office may be an acceptable and efficient approach to preselect candidates for full spirometry testing in primary care. Previous research revealed that a pre-BD FEV1/FEV6 < 0.73 for microspirometry resulted in a negative predictive value of 95.3%.

Objective: To evaluate the added value of a pre-bronchodilator FEV1/FEV6 determination with a microspirometer by the GP in the diagnostic process of COPD and attitude of GPs.

Study design: A cluster-randomised trial with an observation period of six months per participating general practice.

Study population: 22 practices with at least 10 patients each that visited the GP with respiratory complaints that could indicate COPD, are (ex-)smokers and 50 years or older, were not diagnosed with asthma or COPD and did not underwent an spirometric examination in the previous 5 years. GPs of a participating practice will be allocated to the same treatment arm.

Intervention: GPs in the intervention group will be trained in the use of a microspirometer and are asked to execute three pre-bronchodilator FEV1/FEV6 measures with a microspirometer for patients that fulfilled the study population criteria. Patients with a FEV1/FEV6 < 0.73 are recommended to be referred to full spirometry.

Main study parameters/endpoints: The main endpoint of the study is the difference in proportion of eligible patients that completed the diagnostic lung function process within 3 months after the initial GPs' office visit between intervention and usual care group. Secondary outcome include: proportion of patients with an objectified airflow obstruction, GPs attitude towards COPD (diagnosis), a detailed process-evaluation, costs, and accuracy of referrals that were based on microspirometry.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: If a FEV1/FEV6 measure without the administration of a bronchodilator is able to preselect patients with a chronic airway obstruction this could reduce the number of unnecessary full spirometric tests. Patients that visit an intervention practice could be asked to blow three times in a device for 6 seconds. Moreover, patients could be asked to undergo full spirometric examinations that do not differ from regular procedures when a COPD screening is carried out in a general practice. In other words, the burden and risk for the patients are minor and do not differ substantially from regular diagnostic COPD procedures. Only anonymous information of the patients will be collected. Patients are informed on study

participation of the practice with information brochures in the waiting room. The research ethics committee of the Radboud University Nijmegen Medical Centre decided that this study doesn’t fall within the remit of the Medical Research Involving Human Subjects Act (WMO). Therefore, the study can be carried out (in the Netherlands) without an approval by an accredited research ethics committee.

Doel van het onderzoek

Microspirometry result in a higher proportion of diagnostic spirometric assessment to objectify the existence or absence of a chronic airflow obstruction within 3 months after a patients at risk for COPD visited the GP compared to usual care.

Onderzoeksopzet

Baseline assessment, 6 months follow-up.
Endpoint 9 months.

Onderzoeksproduct en/of interventie

GPs will be instructed by an e-learning module on diagnosing chronic airway obstruction/COPD and the role of microspirometry therein, including a practical guide on how to use the microspirometer. Moreover, GPs receive microspirometers that could measure the FEV1/FEV6 ratio. During the 6 months observation time GPs are recommended to use the microspirometer for every patient that fulfilled the selection criteria. Moreover, the GPs are assisted in the use of the microspirometer by the study team at predetermined moments.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

General practices with at least one participating GP.

These GPs will be asked in the intervention group to use the microspirometer for patients who fulfilled the following criteria:

• 50 years or older

• (previous) smoking for at least 3 months

•Respiratory symptoms that could indicate COPD (dyspnoea, cough, mucus, and/or wheezing)

•No previous diagnosis of asthma and/or COPD

•If a lung function test had taken place previously, then this must be at least five years ago.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A general practice who meets any of the following criteria will be excluded from participation in this study:

• Practices that had a full practice list screening for COPD in the last five years.

• General practices in newly-built quarters (i.e., with relatively few older people). A newly-built quarter is defined as build in the last 10 years.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	22
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3880
NTR-old	NTR4041
Ander register	Research ethics committee of the hospital : 2012/483
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A