Pharmaceutical care for asthma patients dependent on their disease control

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24520

Bron
NTR

Verkorte titel
SMARAGD: Self Management Research for Asthma with Good Drug use

Aandoening

Asthma disease control (CARAT, pharmacy dispensing data), medication adherence (MARS, pharmacy dispensing data), inhalation technique (checklist)

Ondersteuning

Primaire sponsor: Radboud university medical centre, Radboud Institute for Health Sciences, IQ Healthcare, Nijmegen, The Netherlands
Overige ondersteuning: Royal Dutch Pharmacists Association, The Netherlands
AstraZeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the patient reported disease control, measured by the CARAT questionnaire.

Toelichting onderzoek

Achtergrond van het onderzoek

Background

The aim of asthma management is to gain and maintain control of the disease. Pharmaceutical care needs to focus on those patients who gain most by additional care of a pharmacist. Furthermore, this care has to be tailored to patients' individual needs. The first step is to identify these patients. Subsequently the pharmacist can intervene , dependent on patients' barriers for effective drug use. Finally, the disease control and the effect of the intervention have to be monitored.

We study the effectiveness of tailored pharmacist interventions to improve asthma control. In this study we use the CARAT on signalizing insufficient or deteriorating asthma control and to enable pharmacists' interventions to prevent exacerbations. Furthermore, we use the questionnaire to evaluate whether devices that remember patients on drug intake support ('technical reminder') regular drug intake.
It is a pilot study, which aims to provide insights needed to design a larger trial.

Methods

This pilot study will be performed in 4 community pharmacies in the South of the Netherlands . Two (randomly chosen) pharmacies will provide usual pharmaceutical care and two pharmacies will provide the interventions.

All patients who meet the inclusion criteria and give informed consent are asked to fill in the CARAT and MARS questionnaires at baseline and after 6 months. Patients in the intervention group receive a structured educational program and will be asked to fill in the CARAT questionnaire every fortnight during 6 months. The pharmacist monitors asthma disease control and contact the patient at low or deteriorating CARAT scores.

A part of all patients will receive a technical reminder.
The primary outcome is the disease control, measured by the CARAT questionnaire.

Doel van het onderzoek

The main objective is to assess the effectiveness of a tailored pharmacist intervention for current users of inhaled corticosteroid (ICS) maintenance therapy to improve the disease

control compared to a control group with usual care.
To tailor the interventions, the disease control is measured during the intervention process by the CARAT. Good drug use is measured by the MARS questionnaire and dispensing data and by assessing inhalation technique. A subgroup will receive a technical reminder for regular drug intake. Furthermore, smoking cessation will be stimulated for current smokers. Results of this pilot study provide insights for designing a larger trial.

Onderzoeksopzet

T = 0: Baseline measurement

T = every fortnight for the intervention group: follow up measurement with CARAT.

T = 6 months: evaluation of all patients

Onderzoeksproduct en/of interventie

All participating pharmacists receive material and written instructions for patient selection, interventions and process registrations.

Patients from both groups are asked to fill in the CARAT and MARS questionnaire at baseline.

Patients in the intervention group are invited in the pharmacy and receive structured education (verbal and written form) by pharmacists on:

- Asthma pathophysiology (Symptoms, triggers)

- Asthma medication

- Dose and time of intake

- Inhalation technique (including physical demonstration by the patient with demo inhaler unit)

- Importance of adherence to maintenance therapy and current problems with adherence

- Possible side effects

- Smoking cessation (if patient is a current smoker)

Patients in the intervention group are asked to fill in the CARAT questionnaire every fortnight. The pharmacist monitors asthma disease control and contact the patient at low or deteriorating CARAT scores.

Patients in the control group receive usual care.

All patients fill in the CARAT and MARS after 6 months.

A part of all patients is eligible for a technical reminder, which reminds patients daily to take their medication at the established time.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients are eligible when meeting following inclusion criteria:

1. Aged 18 years or older

2. Current user of asthma maintenance medication (ICS or combinations of ICS/LABA, at least one prescription in the previous six months)

3. Registered in the pharmacy

4. Willingness to visit the pharmacy and availability for duration of study

5. Current diagnosis of asthma

6. Speak, read and write the Dutch language sufficiently to complete the questionnaires

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with (con)current COPD, patients with low literacy and patients who receive palliative care will be excluded.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-02-2015
Soort:	Eerste indiening

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	NL4959
NTR-old	NTR5063
Ander register	: 2015-1569

Resultaten