Optimising inhaler education in patients with pulmonary disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28559

Source
NTR

Health condition

Asthma or COPD

Sponsors and support

Primary sponsor: Martini Ziekenhuis Groningen
Source(s) of monetary or material Support: no funding, investigator initiated

Intervention

Outcome measures

Primary outcome

The proportion of patients demonstrating adequate inhaler technique.

Secondary outcome

The number of errors while using the inhaler.
Disease control, medication adherence, patient perceived side effects of inhaled cortocosteroids, patient
satisfaction/experiences with the inhaler and instruction provided and satisfaction with the

patient instruction card (in the
usual care + group only).

Study description

Background summary

Inhaled mediation is the cornerstone of the treatment of patients with asthma or COPD. Adequate inhaler technique is
crucial to maximise the benefits of inhaled medication treatment. However, inadequate inhaler technique and device
mishandling is a common and widespread issue. Although device inhaler education has been shown to improve
outcomes, research into the most optimal method or content of inhaler education is scarce. The newly developed inhaler
specific patient instruction cards might be beneficial in optimising inhaler education in patients with obstructive pulmonary
diseases resulting in beneficial effects in the management of patients using inhaled medication. In this randomised controlled trial the additional value of these inhaler specific instruction cards will be assessed in optimising inhaler technique in patients with asthma or COPD. In total 100 patients with asthma or COPD visiting the outpatient department of Pulmonary Diseases of the Martini Hospital Groningen will be included in this study. The study consists of two visits, respectively a baseline visit and a follow up visit (6 to 8 weeks later). At baseline, patients will be randomised to either the usual care group (receiving standard inhaler education: verbally instruction and correct inhaler use will be demonstrated and practised) or the usual care + group (standard inhaler education with an additional inhaler specific instruction card to support the inhaler education. At both visits inhalation technique will be assessed, as well as questionnaires on disease control, medication adherence, patient perceived side effects, patient satisfaction/experiences with the inhaler and instruction provided and satisfaction with the instruction card will be filled out bij the patient. The results of this study will be valuable in optimising the use of inhaled medication and subsequently optimal care for patients with asthma or COPD.

Study objective

Inhaled mediation is the cornerstone of the treatment of patients with asthma or COPD. Adequate inhaler technique is
crucial to maximise the benefits of inhaled medication treatment. However, inadequate inhaler technique and device
mishandling is a common and widespread issue. Although device inhaler education has been shown to improve
outcomes, research into the most optimal method or content of inhaler education is scarce. The newly developed inhaler
specific patient instruction cards might be beneficial in optimising inhaler education in

patients with obstructive pulmonary
diseases resulting in beneficial effects in the management of patients using inhaled medication. The additional value of the use of these inhaler specific instruction cards in inhaler education in patients with asthma or COPD will be evaluated.

Study design

The study consists of two visits, respectively a baseline visit and a follow up visit (6 -8 weeks after baseline).

Intervention

Patients in the usual care group will receive standard inhaler education from a COPD nurse. Instruction will be verbally
provided as well as correct inhaler use will be demonstrated and practised.

Patient in the usual care + group will receive additional to the standard inhaler education a inhaler specific instruction card
to support the inhaler education.

Contacts

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Eligibility criteria

Inclusion criteria

- age 18 years or older

- diagnosis asthma or COPD

- using maintenance medication for pulmonary disease

- signed written informed consent

Exclusion criteria

- received inhaler education in preceding 6 months

- difficulty with understanding the inhalation instruction (cognitive disorder or language problems)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2015
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion
Date: 24-04-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42356
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5056
NTR-old	NTR5187
CCMO	NL52999.099.15
OMON	NL-OMON42356

Study results

Summary results
not yet