Prevalence, incidence and adherence of “difficult-to-treat” adult asthma in the Netherlands.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26986

Source
Nationaal Trial Register

Health condition

prevalence
adherence
difficult-to-treat
asthma
inhalation technique
inhaled corticosteroids

Prevalentie
therapietrouw
astma
inhalatietechniek
corticosteroiden

Sponsors and support

Primary sponsor: Academic Medical Centre, Amsterdam
Source(s) of monetary or material Support: Unrestricted grant by Novartis

Intervention

Outcome measures

Primary outcome

1. The prevalence and incidence of patients with difficult-to-treat asthma in the Netherlands;

2. Factors associated with adherence to pulmonary medication in difficult-to-treat asthma;

3. Primary: Inhalation technique scores in adherent patients with difficult-to-treat asthma;

4. Primary: The proportion of patients with truly severe asthma (i.e. uncontrolled asthma or oral corticosteroid dependent asthma despite good adherence with high dose ICS and adequate inhalation technique).

Secondary outcome

1. Primary: Inhalation technique scores in adherent patients with difficult-to-treat asthma;

2. Secondary: Factors associated with adequate or poor inhalation technique;

4. Primary: The proportion of patients with truly severe asthma (i.e. uncontrolled asthma or oral corticosteroid dependent asthma despite good adherence with high dose ICS and adequate inhalation technique);

4. Secondary: Factors associated with controlled or uncontrolled severe, refractory asthma.

Study description

Background summary

Rationale:

Patients with severe refractory asthma pose a major healthcare problem. It has become increasingly clear that, for the development of new targeted therapies, there is an urgent need for further characterisation and classification of these patients. However, the exact prevalence of patients with severe refractory asthma is unknown and in addition to this, the question remains if patients who have difficult-to-treat asthma have truly severe refractory asthma or are not adherent with their medication or have an incorrect inhalation technique. Data on this is lacking.

Objective:

1. To describe the prevalence and incidence of “difficult-to-treat” adult asthma in the Netherlands.

2. To describe factors associated with adherence with pulmonary medication in patients with difficult-to-treat airway disease.

3. To describe the inhalation technique in adherent patients with difficult-to-treat airway disease.

4. To compare patients’ characteristics of patients with difficult-to-treat asthma with optimal treatment adherence and adequate inhalation technique and severe controlled asthma with optimal treatment adherence and adequate inhalation technique.

Study design:

Descriptive observational study.

Study objective

Aims:

1. To describe the prevalence and incidence of difficult-to-treat adult asthma in the Netherlands;

2. To describe factors associated with adherence with pulmonary medication in patients with difficult-to-treat airway disease;

3. To score the inhalation technique in patients using high dose inhaled corticosteroids who are adherent to treatment;

4. To assess the prevalence of patients with truly severe, refractory asthma and describe the characteristics of these patients.

Study design

N/A

Intervention

All patients listed in 73 community pharmacies and using inhaled corticosteroids will be selected, their characteristics will be encoded and translated into a database. This database will be send to the AMC.

From this database the codes of patients using high dose of inhaled corticosteroids will be selected. The pharmacies will translate these codes to the original patient numbers and send the patients questionnaires. These can be returned directly to the AMC.

From this database containing information about high dose ICS prescription, medication adherence, asthma control and patients characteristics the patients will be divided into 3 categories:

1. Asthma;

2. Mixed asthma/COPD (patients with asthma and ≥ 10py);

3. COPD.

Patients with COPD will be excluded from further analyses and the prevalence and incidence of difficult-to-treat asthma and the adherence to inhaled therapy will be determined.

Additionally, all patients from aim 2 who are adherent with asthma treatment will receive inhalation technique assessment and instructions.

These groups are determined by:

1. Difficult-to-treat asthma;

2. Optimal treatment adherence;

3. Controlled or uncontrolled asthma.

Contacts

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Eligibility criteria

Inclusion criteria

1. All patients using inhaled corticosteroids for at least 3 months at least one receipt repeated;

2. Patients from study 1 using fluticasone equivalent of ≥1000 µg or ≥ 500µg fluticasone equivalent per day + maintenance of 5mg prednisone per day for at least 30 days;

3. Patients from study 2, who have collected ≥70% of prescriptions in the past 12 months.

Exclusion criteria

COPD.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2012
Enrollment:	1500
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-07-2012
Application type:	First submission

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
NTR-new	NL3403
NTR-old	NTR3546
Other	METC AMC : 2011_255
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A