ASTHMA CONTROL COST-UTILITY RANDOMIZED TRIAL EVALUATION.

No registrations found.

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

Summary

ID

NL-OMON22219

Source
Nationaal Trial Register

Brief title
Accurate

Health condition

Asthma

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: - Netherlands Organisation for Health Research and Development (ZON-MW, sub-programme Effects & Costs 80-82310-98-8627)
- Netherlands Asthma Foundation (NAF 3.4.07.044)
- Aerocrine (medical technology company)

Intervention

Outcome measures

Primary outcome

Pharmaco-economics:

1. Net health benefit;

2. Cost-effectiveness;

3. Cost-utility.

Secondary outcome

1. Patient preferences;

2. Compliance;

3. Asthma related quality of life;

4. The number of limited activity days;

5. Exacerbations;

Preplanned subgroupanalyses:

1. Smokers vs. Non-smokers;

2. Asthma control at baseline subdivided into strict, partly, or uncontrolled by Juniper Asthma Control Questionnaire scores of respectively <0.75, 0.75-1.5, >1.5 (Juniper et al. Resp.Med.2006);

3. Exhaled Nitric Oxide status at baseline, subdivided into low(<25), medium(25-50) and high(>50));

4. Allergic vs. non-allergic Asthma;

5. BMI < 30 vs BMI > 30.

Study description

Background summary

Rationale:
The central question is whether an attempt to achieve complete control of all features of asthma, with accompanying high dosis of medication should be made, and whether patients and society value the potential incremental benefit sufficiently to concur with such a

treatment approach. Therefore the aim of the study is to assess patient preferences and cost-effectiveness of two treatment strategies aimed at achieving different levels of clinical control:

1. Partly controlled asthma;

2. Controlled asthma.

A third strategy adds a nitric oxide measurement:

3. Controlled asthma based on exhaled nitric oxide as an additional disease marker.

In the third treatment strategy an algorithm was designed that combines the results of an NO-measurement and the composite score measurements. The question is whether this leads to better asthma control in a general practice population and whether it is a cost-effective addition.

Methods:
720 Patients with mild to moderate persistent asthma from general practices with a nurse practitioner or physician assistant, age 18-50 yr, need for daily treatment with inhaled corticosteroids (more then 3 months usage of inhaled corticosteroids in the previous year), will be identified via primary care patient registries, including Leiden, Nijmegen and Amsterdam areas. The design is a cluster-randomised trial with 40 general practices in all three arms and 12 months follow-up. The patients will visit the general practice at baseline, 3, 6, 9 and 12 months. At each planned and unplanned visit to the general practice treatment will be adjusted with support of an ICT-based asthma monitoring system supervised by a central coordinating specialist nurse. Patient preferences and utilities will be assessed by questionnaire and interview. Data on asthma control, treatment step, adherence to treatment, utilities and costs will be obtained every 3 months. Differences in societal costs (medication, other (health) care and productivity) will be compared to differences in the number of limited activity days and in quality adjusted life years (Dutch EQ5D, SF6D, e-TTO, VAS).

Study objective

1. A treatment strategy aimed at well controlled asthma is more (cost-)effective as compared to a treatment strategy aimed at achieving partly controlled asthma;

2. A treatment strategy aimed at well controlled asthma is (cost-)effective when the treatment step is additionally guided by measurements of exhaled nitric oxide (NO) as compared to a treatment strategy aimed at achieving well controlled asthma or partly controlled asthma.

Study design

Baseline, 3months, 6 months, 9months, 12 months + unplanned visits.

Intervention

1. PC-strategy: aiming to achieve partly controlled asthma based on asthma control measures;

2. C-strategy: aiming to achieve controlled asthma based on asthma control measures;

3. FeNO-strategy: aiming to achieve controlled asthma based on asthma control measures and an indirect marker of airways inflammation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-50 yr;

2. Doctors diagnosis of asthma;

3. A prescription of inhaled corticosteroid treatment in the last year;

4. Willing to change treatment step in order to follow the protocol;

5. Written informed consent.

Exclusion criteria

1. Daily or alternate day oral corticosteroid therapy within 1 month before entering the study;

2. Inability to understand written or oral Dutch instructions;

3. Active diseases likely to interfere with the purpose of the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	720
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-04-2009
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	NL1658
NTR-old	NTR1756
Other	METC LUMC : P08.237
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A