ACCURATE: Asthma Control Cost-Utility RAndomized Trial Evaluation Does exhaled Nitric Oxide improve the aim for asthma control in Primary Care?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32706

Source
ToetsingOnline

Brief title
Cost-utility, patient preferences and FeNO in asthma control

Condition

- Other condition

Synonym
airways obstruction

Health condition

Longaandoening

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw;Astma Fonds

Intervention

Keyword: Cost-Effectiveness-Analysis, Drug-Combinations, Patient-Acceptance-of-Health-Care, Quality-Adjusted-Life-Years

Outcome measures

Primary outcome

The primary end-point is the evaluation of the cost-effectiveness of treatment strategies by incremental net-benefit analysis. Net health benefit addresses cost-effectiveness ratios by assuming values for the willingness-to-pay per unit of effectiveness. Sensitivity analyses will be performed on the perspective (societal versus health care) and the applied utility measure (Dutch EQ5D, SF6D, e-TTO, VAS).

Secondary outcome

The secondary end-points include asthma related quality of life (AQLQ), the number of limited activity days and patient preferences.

Study description

Background summary

despite the availability of effective therapies, asthma remains a source of significant morbidity and use of health care resources. The central question is whether maximal doses of (combination) therapy should be used for long periods in an attempt to achieve complete control of all features of asthma, and whether patients and society value the potential incremental benefit sufficiently to concur with such a treatment approach.

Study objective

The aim of the study is to assess patient preferences and cost-effectiveness of three treatment strategies aimed at achieving different levels of clinical control:
1. controlled asthma
2. partly controlled asthma
3. controlled asthma based on exhaled nitric oxide as an additional disease marker

Study design

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 and at each unplanned visit. 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). The first year will be used for updating the ICT application in order to accommodate the treatment algorithms, preparation and writing of program manuals and internet manuals for distribution to practice nurses, identification of patients and general practices, and the organisation of introductory sessions for practice nurses. During the second and third year the trial will be completed and the second half of the third year will be used for data analysis and preparation of the manuscripts.

Intervention

At each planned and unplanned visit to the general practice the treatment step will be adjusted with support of an ICT-based asthma monitoring system supervised by a central coordinating specialist nurse.

Study burden and risks

The treatment recommendations in current national and international guidelines are largely based on the medical perspective. This hampers the implementation of these guidelines in a real-life setting and this probably explains the disappointing adherence of patients to the guidelines. This project is concerned with the assessment of patients' values and attitudes. This will aid the process of inclusion of patients* values in asthma guidelines and care. Treatment options fall within current guidelines. National guidelines advise

3-monthly visits to the general practice including questions on symptoms, treatment adherence and spirometry [5]. In this study, these visits will be structured. In addition 3-monthly questionnaires will be assessed by the patients at home.
The study needs approval by the Medical Ethics Committee of the Leiden University Medical Center. The subjects will be required to give signed informed consent (Appendix).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria (all of the following criteria)
- age 18-50 yr
- doctors diagnosis of asthma

- patients who need inhaled corticosteroids as controller medication (step 2-4 GINA guidelines)
- inhaled corticosteroids >= 3 months in the previous year
- written informed consent
- no exacerbation of asthma within 1 month before entry

Exclusion criteria

- daily or alternate day oral corticosteroid therapy within 1 month before entering the study
- inability to understand written or oral Dutch instructions
- active diseases likely to interfere with the purpose of the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2009
Enrollment:	720
Type:	Actual

Ethics review

Approved WMO

Date:	04-03-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL24488.058.08