

Clinical and economic implications of stepping down inhaled corticosteroids in patients with chronic stable asthma

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/03/2007	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

The UK national guidelines for asthma management recommend a slow stepwise reduction of treatment in patients with chronic asthma which has been stable for a three to six month period. Inhaled steroids are highly effective in treating asthma, although, a plateau in the therapeutic response may exist for many asthmatic patients at doses below 1000 mcg daily. Concerns have been raised that some patients may be receiving inappropriately high doses of inhaled steroids. The aims of this study are to assess the clinical and economic implications of stepping down inhaled steroid treatment over a one year period on patients with chronic stable asthma receiving more than 1000 mcg inhaled steroid daily.

The primary objectives are:

1. To compare the number of exacerbations of asthma in the group in whom the dose of inhaled steroid is reduced by up to 50% with those in whom the dose is unaltered over a one year period;
2. To perform an economic evaluation of the two management plans. The benefit the proposed investigation may bring to the National Health Service (NHS) is the cost-effective use of inhaled steroid treatment in asthma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval obtained in 1998.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Respiratory tract diseases: Asthma

Interventions

Step down inhaled steroid over one year

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Inhaled steroid

Primary outcome measure

Exacerbation rate

Secondary outcome measures

Inhaled steroid dose

Overall study start date

02/01/1999

Completion date

31/12/2001

Eligibility

Key inclusion criteria

Adult asthmatic patients

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

250

Key exclusion criteria

1. Chronic Obstructive Pulmonary Disease (COPD)
2. Low dose inhaled steroids

Date of first enrolment

02/01/1999

Date of final enrolment

31/12/2001

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Department of Respiratory Medicine

Glasgow

United Kingdom

G12 0YN

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Asthma National Research and Development Programme (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	24/05/2003		Yes	No