

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/03/2007	<b>Condition category</b> 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?
<a href="#">Results article</a>	Results	24/05/2003		Yes	No