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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
23/01/2004		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/03/2007	Respiratory			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**Protocol serial number** 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
- 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

## Study type(s)

Treatment

# 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(s)

Exacerbation rate

# Key secondary outcome(s))

Inhaled steroid dose

## Completion date

31/12/2001

# **Eligibility**

## Key inclusion criteria

Adult asthmatic patients

# Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

**Not Specified** 

# 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

**United Kingdom** 

Scotland

# 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)

# Funder(s)

# Funder type

Government

## **Funder Name**

NHS Asthma National Research and Development Programme (UK)

# **Results and Publications**

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