ISRCTN12335748 https://doi.org/10.1186/ISRCTN12335748

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 19/03/2007	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Neil Thomson

Contact details
Department of Respiratory Medicine
West Glasgow Hospitals University NHS Trust
1053 Gt. Western Road
Glasgow
United Kingdom
G12 0YN
+44 (0)141 211 3241
n.c.thomson@clinmed.gla.ac.uk

Additional identifiers

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

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