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Assessment of long-term efficacy of early introduction of inhaled steroids in asthma

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2016	Respiratory	[ ] Record updated in last year

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
HTA 93/14/99

Study information

Scientific Title
Assessment of long-term efficacy of early introduction of inhaled steroids in asthma

Study objectives
Asthma is one of the commonest chronic diseases in the UK and currently imposes a large economic burden on the NHS. Asthma is often a life-long disease but there are few studies of long-term therapy. Even in its mildest form asthma is associated with chronic inflammation of the airways. Inhaled steroids reduce this inflammation and are highly effective in controlling asthma. Recent evidence suggests that their early introduction may also reduce irreversible changes in airflow obstruction, but larger controlled trials are needed to assess this in both adults and children. The impact of early introduction of inhaled steroids on growth and bone density has not yet been studied adequately in a randomised controlled trial. We propose to study the efficacy of introducing inhaled steroids in children and adults at the time of asthma diagnosis in a randomised controlled trial of parallel group design. The study will be conducted through the MRC General Practice Research Framework, which is currently carrying out a large asthma study coordinated by the applicants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory tract diseases: Asthma

Interventions
Children (3-8 yr) and adults will be randomised to receive either inhaled steroid (budesonide 100µg b.d. in children r 200 µg b.d. in adults) or matched placebo and patients will be followed up at 6 monthly intervals for 4 years, with measurements of peak expiratory flow (over 2 weeks) FEV symptoms, inhaled beta-agonist use, exacerbations and a quality of life assessment. To

measure risks we will measure growth in children and bone density in children and adults. A cost-effectiveness analysis will also be performed. A feasibility study and audit suggest that these patients can be identified and that the procedures are acceptable to both the doctors and patients. This long-term controlled study will provide information about whether very early introduction of inhaled steroids has advantages over the current policy of introducing inhaled steroids when symptoms occur on a daily basis.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
budesonide

Primary outcome measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/02/1999

Completion date
30/04/2004

Eligibility

Key inclusion criteria
Not provided at time of registration.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Not provided at time of registration.

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/02/1999

Date of final enrolment
30/04/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Epidemiology & Medical Care Unit
London
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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