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

Submission date 25/04/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 25/04/2003	**Overall study status** Stopped	
Last Edited 09/08/2017	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peter Barnes

Contact details
University of London
London
United Kingdom
SW3 6LY
+44 (0)20 7351 8174
p.j.barnes@ic.ac.uk

Additional identifiers

Protocol serial number
HTA 93/14/06

Study information

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

Study objectives

We propose to study the effect 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 another large asthma study with the National Asthma Task Force Therapy Working Group. A 21-month feasibility study is proposed in 12-16 practices within the General Practice Research Framework. 100 patients will be recruited (50 adults and 50 children). If the feasibility study is successful and we are awarded the funding for the full study it is hoped that those patients recruited to the pilot study will form the first group of patients in the main study.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/931406

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

Study type(s)
Treatment

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

Interventions
We estimate that for the main trial it will be necessary to recruit 200 adults and 200 children which will require about 160 practices. Children (3-8 years) and adults will be randomised to receive either inhaled steroid (budesonide 100 µg and 200 µg bd.) 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), symptoms, inhaled beta2-agonist use, exacerbations and a quality of life assessment.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
To measure risks we will measure the growth in children and bone density in children and adults. A cost-effectiveness analysis will also be performed.

Key secondary outcome(s))

Not provided at time of registration

Completion date
29/05/1998

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/11/1995

Date of final enrolment
29/05/1998

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of London
London
United Kingdom
SW3 6LY

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration