

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

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/05/2016	Condition category Respiratory	☐ Individual participant data ☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

30/04/2004

Eligibility

Key inclusion criteria

Not provided at time of registration.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

United Kingdom

England

Study participating centre

MRC Epidemiology & Medical Care Unit
London
United Kingdom
NW1 2ND

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