

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

Submission date 25/04/2003	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 25/04/2003	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 09/08/2017	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 93/14/06

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

Primary study design

Interventional

Study design

Randomised controlled trial

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