

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/08/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 93/14/06

## 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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet****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 measure**

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.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

30/11/1995

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

200 adults and 200 children

**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**

England

United Kingdom

**Study participating centre**

**University of London**

London

United Kingdom

SW3 6LY

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Quarry House

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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