

A pragmatic single-blind randomised controlled trial and health economic evaluation of leukotriene receptor antagonists in primary care at steps two and three of the national asthma guidelines

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 11/10/2011	Condition category Respiratory	☐ Individual participant data

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 98/34/05

Study information

Scientific Title

Acronym

ELEVATE

Study objectives

This study will evaluate the relative clinical effectiveness and costs at time points over a two year follow-up (short-term specifically at two months and long-term over two years) of Leukotriene Receptor Antagonist (LTRA) prescription in primary care.

PRIMARY: To compare quality of life with LTRAs against alternative treatments at steps two and three of the guidelines, comparing resource use over a two year period to the NHS and patients (on an intention to treat basis), using either a cost-minimisation or cost-effectiveness approach. The choice will depend on whether differences emerge between the groups over two years with particular emphasis on two months and two years (i.e. short and long-term).

SECONDARY: To compare other clinically relevant asthma outcomes between two treatment groups at two months and throughout the two year study (see Primary outcomes).

The design enables this to be compared at step two with inhaled steroid prescription and at step three with add-on of a long-acting beta agonist prescription. Its pragmatic design coupled with clinical trial rigour:

1. Concealed randomised allocation of patients,
2. Blinded procedures for recording and collection of outcomes data (by a non-clinician) and blinded data analysis should produce results that are both valid and applicable to primary care as a whole.

Please note that, as of 25 January 2008, the start and end dates of this trial were updated from 1 January 2000 and 30 April 2003 to 1 October 2001 and 28 February 2007, respectively.

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

Asthma

Interventions

LTRAs versus alternative treatment

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Leukotriene receptor antagonist

Primary outcome(s)

1. Need for further treatment intervention
2. Frequency of exacerbations
3. Short-acting beta agonist use
4. Hospitalisations
5. Time off work
6. Daily inhaled steroid dose (step three)
7. Asthma symptoms
8. Morning and diurnal variation in peak flow
9. Those with eczema/rhinitis comparative change in disease assessment

Key secondary outcome(s)

Not provided at time of registration.

Completion date

28/02/2007

Eligibility**Key inclusion criteria**

Not provided at time of registration.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/10/2001

Date of final enrolment

28/02/2007

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Department of General Practice & Primary Care

Aberdeen

United Kingdom

AB25 2AY

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Beta-2 results	01/10/2010		Yes	No
Results article	Corticosteroid results	01/10/2010		Yes	No
Results article	results	01/05/2011		Yes	No
Results article	results	05/05/2011		Yes	No