ISRCTN99132811 https://doi.org/10.1186/ISRCTN99132811

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

Registration date
25/04/2003

Overall study status
Completed

Last Edited
11/10/2011

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/10/2001

Completion date
28/02/2007

Eligibility

Key inclusion criteria

Not provided at time of registration.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
720

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
Scotland

United Kingdom

Study participating centre
Department of General Practice & Primary Care
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Sponsor information

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Sponsor type
Government

Website
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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

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