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A comparison study of leukotriene receptor antagonist plus topical nasal steroid versus oral antihistamine + topical nasal steroid versus leukotriene receptor antagonist + oral antihistamine + topical nasal in the treatment of perennial allergic rhinitis

Submission date
12/09/2003

Recruitment status
Stopped

Registration date
12/09/2003

Overall study status
Stopped

Last Edited
18/11/2009

Condition category
Respiratory

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0547111166

Study information

Scientific Title

Study objectives
How effective is leukotriene receptor antagonist plus topical nasal steroid versus oral antihistamine + topical nasal steroid versus leukotriene receptor antagonist + oral antihistamine + topical nasal steroid in the treatment of perennial allergic rhinitis?

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory: Allergic rhinitis

Interventions
Patients are randomised into one of three groups:
Group 1: leukotriene receptor antagonist plus topical nasal steroid
Group 2: oral antihistamine plus topical nasal steroid
Group three: leukotriene receptor antagonist, oral antihistamine plus topical nasal steroid

Added 18/11/09: trial stopped due to lack of resources.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Leukotriene receptor antagonist, oral antihistamine, topical nasal steroid

Primary outcome measure
Symptom scores at 12 week assessment

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2002

Completion date
01/07/2004

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
60 patients (20 in each group), patients seen in out-patients with symptoms, signs and test results consistent with perennial allergic rhinitis will be placed on a six-week course of topical nasal steroid spray.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/2002

Date of final enrolment
01/07/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
ENT Department
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
East Norfolk and Waveney Research Consortium - Norfolk and Norwich University Hospital /Norwich PCT (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