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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 18/11/2009	**Condition category** Respiratory	

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

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

Study type(s)
Treatment

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(s)
Symptom scores at 12 week assessment

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre

ENT Department
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Department of Health (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration