

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
Registration date 12/09/2003	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 18/11/2009	Condition category Respiratory	☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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