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A double blind randomised placebo controlled study to evaluate the efficacy of Enzyme Potentiated Desensitisation (EPD) in seasonal rhinitis

Submission date
23/01/2004

Registration date
23/01/2004

Last Edited
07/12/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Ear, Nose and Throat

[_] 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

Protocol serial number
SEO131

Study information

Scientific Title

Study objectives
Is enzyme potentiated desensitisation significantly superior to an identical placebo treatment when administered pre-seasonally to hay fever sufferers?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Southwest England Multicentre Research Ethics Committee (MREC) and several local research ethics committees.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Seasonal rhinitis

Interventions
Patients randomised to receive two injections out of hay fever season, either EPD or placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Enzyme Potentiated Desensitisation (EPD)

Primary outcome(s)
Measured during 12 week hay fever season: number of problem free days and post-treatment symptom scores.

Key secondary outcome(s))
No secondary outcome measures

Completion date
14/08/2001

Eligibility

Key inclusion criteria

1. To be recruited from GP lists aged 18 - 64 years
2. Either sex
3. History of seasonal allergic rhinitis extending mid-May to end-July
4. Positive skin prick test to mixed grass pollens

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Symptoms of sufficient severity to require regular treatment outside usual grass-pollinating season
2. History of predominant seasonal problem not corresponding with usual grass-pollinating season
3. Rhinitis complicated by nasal infection, rhino-sinusitis, nasal polyps, septal deviation, gross turbinate hypertrophy or intranasal mass
4. History of anaphylaxis or laryngeal oedema
5. Undergoing nasal surgery within 2 months
6. Receiving specific immunotherapy (high dose method) within preceeding 12 months

Date of first enrolment
14/05/2000

Date of final enrolment
14/08/2001

Locations

Countries of recruitment
United Kingdom

Study participating centre
Complementary Therapy Centre
Southampton
United Kingdom
SO14 OYG

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (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	Results	05/12/2007		Yes	No