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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	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/12/2007	Ear, Nose and Throat	

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Measured during 12 week hay fever season: number of problem free days and post-treatment symptom scores.

Secondary outcome measures
No secondary outcome measures

Overall study start date
14/05/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

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