

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/12/2007	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr George Lewith

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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?
<a href="#">Results article</a>	Results	05/12/2007		Yes	No