

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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.

Primary study design

Interventional

Study design

Randomised controlled trial

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