

# Intradermal allergen immunotherapy in adults with seasonal allergic rhinitis

<b>Submission date</b> 19/11/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/12/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

We are performing a study of a new vaccine treatment for hay fever, which affects 1 in 4 people in the UK. Injection of small quantities of grass pollen high up in the skin (in an area called the dermis) provokes a local allergic response, visible as a lump lasting a day or two. When these injections are repeated every 2 weeks, a dramatic reduction is seen in the size of this lump, suggesting that the allergic reactions are being switched off. Our aim is now to test if this also switches off grass allergy in the nose and improves hay fever symptoms.

### Who can participate?

Adults aged 18 to 65 with hay fever.

### What does the study involve?

Participants will be randomly divided into two groups to receive either injections of grass pollen into the dermis, or similar placebo (dummy) injections, before the grass pollen season. In the summer, participants will score their symptoms and how much hay fever medication they need. We will then compare these scores in the two groups. We will also perform experiments to see how this 'vaccine' might work: we take blood samples at the beginning and end of the study for experiments. Also, we will collect a small sample of skin, but only from 40 of the participants selected at random, although they will free to decline this. We will also perform tests to examine if the effect of the vaccine is long lasting.

### What are the possible benefits and risks of participating?

This study may define a new scientific and clinical principle that could also be applied to other allergic diseases such as asthma and food allergies. We believe that these injections are safe, although we will observe all participants for 1 hour after the first injection and for 30 minutes after subsequent injections.

### Where is the study run from?

King's College London (UK).

### When is the study starting and how long is it expected to run for?

From September 2012 to March 2013.

Who is funding the study?  
NIHR Evaluation, Trials and Studies Coordinating Centre (UK).

Who is the main contact?  
Dr Stephen Till  
stephen.till@kcl.ac.uk

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2012-002193-31

**Protocol serial number**  
12950

## Study information

**Scientific Title**  
A randomised, double-blind, single-centre, controlled trial of low dose intradermal allergen immunotherapy in adults with seasonal allergic rhinitis

**Acronym**  
PollenLITE

**Study objectives**  
The primary objective is to determine if pre-seasonal low dose intradermal grass pollen allergen immunotherapy (either 7 or 8 two-weekly injections of 10 Biological Units (33.333 SQ-U)) reduces symptoms and requirements for anti-allergic drugs in seasonal allergic rhinitis during the 2013 grass pollen season compared to the control intervention (histamine only).

### Secondary objectives:

1. Determine if this intervention is associated with improvement in quality of life compared to the control intervention, as assessed during the 2013 grass pollen season.
2. Evaluate if this is a safe and well-tolerated form of treatment.
3. Investigate immunological mechanisms associated with this form of treatment, by examining humoral and cellular responses, both in peripheral blood and in tissue.
4. Explore if the intradermal desensitisation effect is long-lived i.e. persists following cessation of intradermal injections.

More details can be found at: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12950>

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

First MREC, 25/07/2012 ref: 12/LO/0941

### Study design

Randomised interventional trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Respiratory disease

### Interventions

Intradermal Injections:

1. Active: grass pollen extract
  2. Control: histamine
- Follow-up length: 24 months

### Intervention Type

Biological/Vaccine

### Primary outcome(s)

Combined symptom/medication score measured at summer 2013

### Key secondary outcome(s)

No secondary outcome measures

### Completion date

21/03/2013

## Eligibility

### Key inclusion criteria

1. Adults aged 18 to 65 years
2. A clinical history of grass pollen-induced allergic rhinoconjunctivitis for at least 2 years with peak symptoms in May, June, or July.
3. A clinical history of moderate-severe persistent rhinoconjunctivitis symptoms interfering with usual daily activities or with sleep.
4. A clinical history of rhinoconjunctivitis that remains troublesome despite treatment with either antihistamines or nasal corticosteroids during the grass pollen season.
5. Positive skin prick test response, defined as wheal diameter greater than or equal to 3 mm, to *Phleum pratense*.
6. Positive specific IgE, defined as greater than or equal to IgE class 2, against *Phleum pratense*.
7. For women of childbearing age, a willingness to use an effective form of contraception for the duration of intradermal injections.
8. The ability to give informed consent and comply with study procedures
9. Male or female

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Pre-bronchodilator FEV1 less than 70% of predicted value at screening visit
2. A history of seasonal grass pollen-induced asthma requiring regular treatment with salbutamol or inhaled corticosteroids. Patients with mild seasonal grass pollen-induced asthma may be included, provided symptoms are satisfactorily controlled with occasional salbutamol only.
3. A clinical history of symptomatic seasonal allergic rhinitis and/or asthma due to tree pollen or weed pollen near or overlapping the grass pollen season.
4. A clinical history of symptomatic allergic rhinitis and/or asthma caused by a perennial allergen to which the participant is regularly exposed.
5. Emergency department visit or hospital admission for asthma in the previous 12 months.
6. History of chronic obstructive pulmonary disease.
7. History of significant recurrent acute sinusitis, defined as 2 episodes per year for the last 2 years, all of which required antibiotic treatment.
8. History of chronic sinusitis, defined as a sinus symptoms lasting greater than 12 weeks that includes 2 or more major factors or 1 major factor and 2 minor factors. Major factors are defined as facial pain or pressure, nasal obstruction or blockage, nasal discharge or purulence or discoloured postnasal discharge, purulence in nasal cavity, or impaired or loss of smell. Minor factors are defined as headache, fever, halitosis, fatigue, dental pain, cough, and ear pain, pressure, or fullness.
9. At randomisation, current symptoms of, or treatment for, upper respiratory tract infection,

acute sinusitis, acute otitis media, or other relevant infectious process; serous otitis media is not an exclusion criterion. Participants may be re-evaluated for eligibility after symptoms resolve

10. Current smokers or a history of greater than or equal to 5 pack years

11. Previous treatment by immunotherapy with grass pollen allergen within the previous 5 years

12. History of life-threatening anaphylaxis or angioedema

13. Ongoing systemic immunosuppressive treatment

14. History of intolerance of grass pollen immunotherapy, rescue medications or their excipients

15. For females of childbearing age a positive serum or urine pregnancy test with sensitivity of less than 50 mIU/mL within 72 hours of first administration of study therapy

16. Lactating females

17. The use of any investigational drug within 30 days of the screening visit

18. Ongoing treatment with beta-blockers, calcium channel blockers, tricyclic antidepressants, monoamine oxidase inhibitors or anti-IgE monoclonal antibody

19. The presence of any medical condition that the investigator deems incompatible with participation in the trial

20. Individuals with insufficient understanding of the trial

#### **Date of first enrolment**

18/02/2013

#### **Date of final enrolment**

21/03/2013

## **Locations**

#### **Countries of recruitment**

United Kingdom

England

#### **Study participating centre**

**King's College London**

London

United Kingdom

SE1 9RT

## **Sponsor information**

#### **Organisation**

King's College London (UK)

#### **ROR**

<https://ror.org/0220mzb33>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Evaluation, Trials and Studies Coordinating Centre (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?
<a href="#">Results article</a>	results	01/12/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No