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Intradermal allergen immunotherapy in adults with seasonal allergic rhinitis

Submission date 19/11/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 19/11/2012	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 20/12/2017	**Condition category** Respiratory	[_] 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2012-002193-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Combined symptom/medication score measured at summer 2013

Secondary outcome measures
No secondary outcome measures

Overall study start date
20/09/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 90; Description: 45 active, 45 control

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
England

United Kingdom

Study participating centre
King's College London
London

United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Coordinating Centre (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	01/12/2016		Yes	No
HRA research summary			28/06/2023	No	No