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Can we help people with Oral Allergy Syndrome eat fresh fruit?

Submission date
03/10/2012

Recruitment status
No longer recruiting

Registration date
04/10/2012

Overall study status
Completed

Last Edited
09/04/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Birch pollen allergy is increasingly common. It causes asthma and early season hay fever. This is because the body recognises birch pollen and reacts to it, leading to symptoms. Many patients with birch allergy get an itchy and/or swollen mouth when they eat fresh fruit (apples, pears, peaches, plums etc). Some fruit proteins have a similar structure to birch pollen; because of this the body recognises these proteins too causing the immune system to respond. This response causes symptoms of itch and swelling inside the mouth and throat. We want to find out whether we can get rid of the fruit-induced symptoms by using a desensitisation procedure that has been developed for treating the kind of hay fever that is caused by birch pollen. Desensitisation involves giving a small injection of pollen just under the skin and gradually increasing the amount each week. This allows the body to build up a tolerance to the injected protein. When the pollen is then encountered in real life the immune system reacts less vigorously so symptoms are less severe. This treatment does reduce hay fever symptoms. Our study aims to find out if this tolerance is transferred to the fruit proteins enabling patients to eat apples with minimal symptoms.

Who can participate?
50 patients with hay fever and oral allergy symptoms will be recruited to the trial. Anyone male or female from the age of 18 upwards can take part as long as they have no other significant diseases.

What does the study involve?
Patients will be given apple to eat in a hidden form before treatment and their response assessed. They will then receive either active or dummy pollen injections before birch pollen season. A few months after completing these injections they will have another disguised apple test to see whether their symptoms are any better.

What are the possible benefits and risks of participating?
If symptoms have improved with treatment then this therapy could be offered to patients in the future. This would allow them to eat fresh fruit without worrying about unpleasant symptoms and improve their hay fever symptoms. The study drug itself has previously been tested in humans, is in routine use for hay fever and is not experimental in any way. Its effect on fruit

allergy is less certain. Therefore we cannot guarantee patients will respond to treatment. Furthermore there is a chance patients will receive the dummy drug. As the desensitisation injections do contain pollen proteins, to which we know patients are allergic, there is a risk of causing an allergic reaction. This may be mild and only affect the area that was injected, causing localised swelling and redness, or may be more severe causing wheeze, breathlessness or in extreme cases anaphylaxis. The injections are only given by doctors, who are trained to recognise such side effects, and the reactions are all completely treatable.

Where is the study run from?
The study will be run from the Clinical Investigation and Research Unit (CIRU) at the Royal Sussex County Hospital

When is study starting and how long is it expected to run for?
The study started recruiting in August 2012 and is expected to run for two years.

Who is funding the study?
The study is funded by Research for Patient Benefit Grant from the NIHR.

Who is the main contact?
Dr Nicola Gray, Clinical Research Fellow at CIRU
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01431859

Clinical Trials Information System (CTIS)
2011-004078-26

Protocol serial number
11277

Study information

Scientific Title
A double blind placebo controlled randomised trial to study the effects of birch pollen specific immunotherapy (BPSIT) on the symptoms of the oral allergy syndrome in adult patients

Acronym
OAS

Study objectives
Birch pollen allergy causes early season hay fever and asthma. Up to two thirds of birch pollen-allergic patients experience oropharyngeal itching, irritation and swelling on eating fresh fruits and vegetables [known as oral allergy syndrome or (OAS)] This is due to sensitisation to panallergen molecules that are common to both pollen and fruits. It is well established that patients with birch pollen allergy can be desensitised, using vaccines containing birch pollen extracts. Given the immunological basis of the OAS, it seems possible that desensitising the patient to birch pollen might abolish or attenuate OAS.

We will recruit 50 patients with early season hay fever who report fruit-related symptoms. Patients will be allocated to active or placebo intervention using block randomisation. 25 patients will be assigned to placebo and 25 to treatment arms. The primary outcome is a change in the threshold of fresh apple than can be eaten by the subject. This will be reviewed after one and two seasons of immunotherapy. Any differences between the two seasons will be recorded. This change will be assessed by a series of double blind food challenge tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central Berkshire, 22/11/2011, ref: 11/SC/0448

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Inflammatory and Immune System, Respiratory; Subtopic: Not Assigned, Inflammatory and Immune System (all Subtopics), Respiratory (all Subtopics); Disease: Immunology and inflammation, Respiratory, All Diseases

Interventions
Patients will be randomly assigned to placebo or to treatment arm

Immunotherapy: Sub cutaneous birch pollen specific immunotherapy

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
A change in tolerance to fresh apple, 1 year and 2 years post immunotherapy

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Male or female; age 18 with no upper age limit
2. History of typical fruit-related symptoms on eating apples plus or minus other plant-derived foods known to be involved in the pollen-food syndrome
3. History of spring rhinitis hay fever
4. Positive skin prick test to birch pollen
5. Positive open food challenge to apple

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Inadequately controlled or moderate to severe asthma (GINA III/IV), i.e. the FEV1 is below 70 % of the target value despite adequate pharmacotherapy
2. Irreversible changes in the reaction organ (emphysema, bronchiectasis, etc.)
3. Clinically significant cardiovascular insufficiency (in cardiovascular diseases, there is an elevated risk of adverse reactions to adrenaline)
4. Local or systemic use of beta blockers
5. History of moderate to severe systemic reaction to apple, defined as any of: generalised urticaria, generalised angioedema, history convincing for laryngeal oedema, collapse
6. Diseases of the immune system (autoimmune diseases, immune complex-induced

immunopathies, immunodeficiencies etc.)
7. Malignant disease within the past five years (Patients with previous malignant disease that is considered cured may be included subject to the consent of their oncologist)
8. Inability to attend regularly for injections and follow-up visits
9. Severe atopic dermatitis
10. Previous immunotherapy with birch pollen extract
11. Pregnant or not using adequate contraception (post-menopausal, surgically sterilised, long-term abstinent, or barrier methods plus spermicide)
12. Breast-feeding
13. Evidence of current drug or alcohol misuse
14. Hypersensitivity to any of the BP-SIT exipients
15. Active tuberculosis
16. Severe mental disorders
17. Multiple sclerosis
18. Patients with an acute febrile illness should not be included in the study but they may take part once they have recovered.

Date of first enrolment
01/09/2012

Date of final enrolment
19/11/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Sussex County Hospital
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust

Organisation
Royal Sussex County Hospital

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB) (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?
Basic results			28/05/2020	No	No
HRA research summary			28/06/2023	No	No