

Maintenance versus pre-seasonal allergoid immunotherapy in seasonal allergic rhinitis

Submission date 22/09/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/10/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/10/2016	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Hay fever (seasonal allergic rhinitis) is a common allergic condition caused by pollen. Allergen immunotherapy (sometimes called desensitisation treatment) is a treatment that involves giving the patient increasing doses of grass pollen. It is recommended for patients when drug treatment does not bring satisfactory results. Allergen immunotherapy reduces both allergy symptoms and the quantity of drugs prescribed. It is usually given to a patient for three to five years. The treatment can be given by injection (subcutaneous immunotherapy), or by drops placed under the tongue (oral immunotherapy). Two different types of subcutaneous immunotherapy are most frequently used in hay fever patients, pre-seasonal and maintenance, but no studies have compared these two methods so far. The aim of this study is to compare the effects of three-year maintenance and pre-seasonal subcutaneous immunotherapy on patients with hay fever.

Who can participate?

Hay fever patients over five years of age from the Bialystok region (Poland)

What does the study involve?

A detailed history is collected from every participant and a physical examination is performed. Skin prick tests are performed with 11 common allergens, along with breathing tests. Participants are randomly allocated to either maintenance or pre-seasonal subcutaneous immunotherapy with a vaccine made from six grass pollens. In both groups, immunotherapy begins with a build-up phase, gradually reaching the maintenance dose of the vaccine in 7 to 14 day intervals. After reaching the maintenance dose, this dose is administered every two to four weeks in the pre-seasonal group and every four to six weeks in the maintenance group. Every year before the pollen season, patients from the pre-seasonal group are given a package containing 10 injections of the vaccine. Patients from the maintenance group, after reaching a well-tolerated dose, are given booster injections for a period of three years. These two groups are compared in terms of breathing changes caused by breathing in a grass-pollen mixture. This test is performed before starting subcutaneous immunotherapy and yearly thereafter, between November and January.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Medical University of Bialystok (Poland) (ref: 3-18503P)

When is the study starting and how long is it expected to run for?
October 2005 to December 2009

Who is funding the study?
Medical University of Bialystok (Poland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
3-18503P

Study information

Scientific Title
Maintenance versus pre-seasonal allergoid immunotherapy in seasonal allergic rhinitis: a randomized trial

Study objectives
Pre-seasonal and maintenance protocols of subcutaneous immunotherapy differ in regards to the type and severity of bronchial response during bronchial challenge in seasonal allergic rhinitis subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical University of Bialystok (Poland), 30/11/2006, ref: R-I-003/299/2006

Primary study design

Interventional

Study design

Randomized open trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Seasonal allergic rhinitis

Interventions

In both arms, immunotherapy will begin with a build-up phase, i.e. gradually reaching the maintenance dose (increasing volumes of 0.1 ml, 0.2 ml, 0.4 ml and 0.8 ml will be administered subcutaneously in 7 to 14 day intervals from vial A containing 1000 TU/ml of allergoid, followed by 0.15 ml, 0.30 ml and 0.6 ml from vial B containing 10000 TU/ml of allergoid). After reaching the maintenance dose, usually equal to 6000 TU of allergoid, this dose will be administered every two to four weeks or every four to six weeks in the pre-seasonal and maintenance arms, respectively. Every year before the pollen season, patients from the pre-seasonal arm will be given one package (one vial of A and B), usually divided into 10 injections, corresponding to 30000 TU yearly dose of allergoid. Patients from the maintenance arm, after reaching a well-tolerated dose not exceeding 0.6 ml, will be given booster injections for a period of three years.

Intervention Type

Biological/Vaccine

Primary outcome(s)

1. Bronchial response distributions after bronchial allergen challenge (BAC)
2. Provocative concentration causing a 20% fall in forced expiratory volume in one second (PC20FEV1)
3. Maximal decrease in forced expiratory volume in one second (FEV1) determined during late asthmatic response

Key secondary outcome(s)

Nitric oxide concentration in exhaled air (FeNO) determined prior to and after bronchial allergen challenge (BAC)

Completion date

31/12/2009

Eligibility**Key inclusion criteria**

1. History of seasonal allergic rhinitis
2. Confirmed sensitivity to grass pollen
3. More than five years of age
4. Ability to proper performance of spirometry

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Current or past active and passive tobacco-smoking

Date of first enrolment

01/10/2005

Date of final enrolment

31/12/2009

Locations**Countries of recruitment**

Poland

Study participating centre

Medical University of Bialystok

Bialystok

Poland

15-274

Sponsor information**Organisation**

Medical University of Bialystok (Poland)

ROR

<https://ror.org/00y4ya841>

Funder(s)

Funder type

University/education

Funder Name

Uniwersytet Medyczny w Białymstoku

Alternative Name(s)

Medical University of Białystok

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Poland

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	01/06/2012		Yes	No