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# Maintenance versus pre-seasonal allergoid immunotherapy in seasonal allergic rhinitis

**Submission date**
22/09/2011

**Recruitment status**
No longer recruiting

**Registration date**
10/10/2011

**Overall study status**
Completed

**Last Edited**
12/10/2016

**Condition category**
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Prof. Zenon Siergiejko
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Zenon Siergiejko

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Study design
Randomized open trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Treatment

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

## 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 measure

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

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

### Overall study start date
01/10/2005

### 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

### Age group
Mixed

### Sex
Both

### Target number of participants
60

### 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)

**Sponsor details**
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Bialystok
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**Sponsor type**
University/education

**Website**
http://ed.umb.edu.pl/

**ROR**
https://ror.org/00y4ya841

# Funder(s)

**Funder type**
University/education

**Funder Name**
Uniwersytet Medyczny w Bialymstoku

**Alternative Name(s)**
Medical University of Bialystok

**Funding Body Type**
Government organisation

### Funding Body Subtype
Local government

### Location
Poland

## 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 | 01/06/2012 | | Yes | No |