A double blind randomized placebo controlled study on the efficacy of intralymphatic immunotherapy in the treatment of grasspollen induced allergic rhinitis.

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In this study we will compare the effect of intra nodal allegen injection with grass pollen to the intra nodal injection with placebo on symptome scores of allgic rhinitis (hay fever) in grass allergic patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON39544

Source
ToetsingOnline

Brief title
ILIT

Condition

- Allergic conditions
- Upper respiratory tract disorders (excl infections)

Synonym
Allergic rhino-conjunctivitis, hayfever

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Stichting wetenschappelijk onderzoek KNO Den Haag

Intervention

Keyword: Allergy, Grass, Immunotherapy, Lymphenode

Outcome measures

Primary outcome

Primary study outcome measure will be the level of allergic symptoms (VAS

score) following intra nasal grass pollen provocation in patients treated with

Alutard grass pollen compared with the results for patients treated with

placebo.

Secondary outcome

changes in allergic skin prick test reactivity pre and post immunisation

between the groups

changes in serologic allergy tests pre and post immunisation between the groups

changes in serum IgE and Ig4 levels pre and post immunisation between the groups

changes in cellular infiltrates in the nasal mucosa pre and post immunisation

between the groups

Study description

Background summary

Allergic rhinitis is a globally occurring disease with a still increasing incidence. The mainstay of treatment is the aimed at symptom reduction using local or systemic medication. A second treatment modality consists of immunotherapy in which symptom reduction is achieved by modulating the immune

system. Current immunotherapy protocol make use of intadermal injection or sublingual allergen application. These protocols necessitate prolonged participation of patients for up to three years. This gives rise to a high amount of therapy drop out / failure.
A new approach to allergen sentisation using a shorter strategy of allegen application wil improve therapy results and overall costs. Intra lymphatic application of allergens is such a new strategy with promissing results.

Study objective

In this study we will compare the effect of intra nodal allegen injection with grass pollen to the intra nodal injection with placebo on symptome scores of allgic rhinitis (hay fever) in grass allergic patients.

Study design

25 patients suffering from allergic rhinitis to grass pollen will receive 3 consecutive intranodal injection with grass pollen (Alutard) in the groin region. These injections will be given once a month. 25 patients in the control group will receive placebo injections in a similar fashion. Prior to allergen injections the level of allergic complaints will be scored using a intranasal provocation test. Two months after final injection a similar intra nasal provocation test will be performed. Differences in allergen provocation reactivity (VAS scores) in pre and post immunotherapy nasal provocation tests, will be compared between the groups.

Intervention

allergen provocation tests
blood sampels
nasal biopsy
intranodal groin injection

Study burden and risks

All participating patients will undergo extra test which are not direct related to the standard treatment protocol for immunotherapy. The extra tests consist of one additional allergic skin test, intranasal allergen provocation twice and one additional blood sample. These test can give rise to mild local allergic reaction (itching of the skin, redness and / or swelling of the skin, sneezing and itching of nose / eyes. More invasive tests are biopsy of the nasal mucosa which can cause minor nose bleeds in some cases and can be treated with minimal discomfort. The intra nodal injection in the groin area can cause mild local skin reactions. Systemic allergic reaction (anafylactic shock, astma exacerbation) to allergen provocation have been sporadically reported. However in literature no such effect have been reported in the case of intranodal

injection. To prevent the occurrence of these effects patients with instabel asthma will be excluded from participation. Furthermore allergic sensitization will be performed at the department of radiology. This department is by nature triggered to detect and if necessary treat allergic systemic reactions (anaphylaxis due to contrast allergy).

Contacts

Public
HagaZiekenhuis

Leyweg 275 Leyweg 275
Den Haag 2545CH
NL
Scientific
HagaZiekenhuis

Leyweg 275 Leyweg 275
Den Haag 2545CH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Sensibilisation to grass pollen
age between 18 and 50 years old
Informed consent

Exclusion criteria

No informed consent
instable or steroidtherapy dependent atopic astma
rhinosinusitis
nasal polyps
vasomotore rhinitis
immunosupressive medication
immuondeficiancy (IgG-IgA deficiaccy, HIV-AIDS)
pregnany or nursing
participation in other medical study
history of desensibilisation therapy
Significant cardiovascular disease
Severe impaired renal function
Hypersensitivity to aluminiumhydroxid
Childeren untill age of 18
Blood donation within previous 30 days
Surgery within the previous 30 days
Use of investigational drugs within previous 90 days
Mastocytosis
Hypertension
Active infectious disease
Significant hepatic disease
Significant renal disease
Significant hematological disorder
Significant pulmonary disease
Moderate or severe asthma
Autoimmune disease
History of malignancy.
Contraindicated medications were immunosuppressive agents, beta-blockers, ACE-inhibitors, and tricyclic antidepressants.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2011
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Alutard SQ 1000 SQ-U /ml
Generic name:	Alutard
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	25-05-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	13-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-017761-36-NL
CCMO	NL28838.098.11