The effect of Citrus/Cydonia comp.® on hay fever

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

Summary

ID

NL-OMON33622

Source
ToetsingOnline

Brief title
SuNa Hay Fever pilot study

Condition

- Allergic conditions

Synonym
grass pollen allergy, hay fever

Research involving
Human

Sponsors and support

Primary sponsor: Weleda AG
Source(s) of monetary or material Support: Weleda Internationaal

Intervention

Keyword: clinical trial, grass pollen allergy, immuno therapy

Outcome measures

Primary outcome

- immunological parameters:

- IL-10,

- IL-12,

- IFN-g,

- IL-4, en

- IL-5

Secondary outcome

- symptom scores:

- total symptom scores,

- total non-nasal symptom scores, and

- nasal symptom scores

- adverse events

Study description

Background summary

Considering the high prevalence of allergic rhinitis and the fact that a significant number of sufferers with severe symptoms are resistant to treatment with usual pharmacotherapy (antihistamines and topical nasal corticosteroids) (Wilson et al., 2005), there still is a space and need for the development of new treatment concepts.
Citrus/Cydonia comp. is an anthroposophic medicine, which contains lemon juice (Citrus limon, succus) and a aqueous extract from quince (Cydonia oblonga, fructus rec., 1:2.1). For over eighty years now, Citrus/Cydonia comp. is being

prescribed as a subcutaneous injection or as a nasal spray for patients who suffer from seasonal allergic rhinitis. In several European countries, Citrus/Cydonia comp. is commercially available under the trade name *Gencydo®* for the prophylaxis and treatment of allergic diseases, specifically those affecting the respiratory tract such as hay fever.

A survey on clinical experiences, carried out among a group of 39 general practitioners in the Netherlands, indicates that the subcutaneous treatment with Citrus/Cydonia comp. ampoules is profoundly effective (Bruin et al., 2001). Firstly, a permanent effect from the treatment with Citrus/Cydonia comp. tends to be experienced, which indicates that the patients in question are claiming to lastingly suffer less from hay fever or even that they are free from complaints. Secondly, the effect is occurring within a period of two weeks, up to three months, after the actual treatment. Thirdly, the effect is optimal after a treatment of several years. In a therapeutic causality report, positive effects with Citrus/Cydonia comp. were observed in a group of 13 patients suffering from grass pollen mediated hay fever (Baars et al., 2005). In most patients, Citrus/Cydonia comp. injections were given before the onset of and during the grass pollen season and symptom severity did not increase during the pollen season. Furthermore, 69% of the patients reported an improvement of symptoms. In addition, a prospective, observational study on the effect of Citrus/Cydonia comp. nasal spray on hay fever symptoms reported positive results without side effects in 140 patients (Rother and Oexle, 2008). Recently, the immunological pathways underlying the positive effects of Citrus/Cydonia comp. in patients with seasonal allergic rhinitis were studied (Baars and Savelkoul, 2008). Therefore, peripheral blood mononuclear cells (PMBCs) were isolated from a healthy and an allergic donor and the effect of Citrus/Cydonia comp. on differentiation capacity and Th1 (e.g. IFN-*) and Th2 (e.g. IL-5) cells was examined. Citrus/Cydonia comp. showed a selective effect on the differentiation of T-cells by producing relatively more IL-10 than IL-12. Furthermore, it also had an effect on the induction of regulatory (IL-10 producing) T-cell subsets. It was therefore concluded that Citrus/Cydonia comp. can potentially restore the disturbed immune state of allergic rhinitis patients by modulation of the Th1-Th2 balance. This immunotherapeutic potency and the positive results from the observed clinical cases, form the rational to further evaluate the effects of Citrus/Cydonia comp. in seasonal allergic rhinitis.

The tolerability and safety of Gencydo nasal spray was investigated in a prospective observational study with 140 patients (Rother and Oexle, 2008). Furthermore, between January 1997 and December 2005, 3.1 million single doses of injection preparations were sold. Between April 1997 and July 2006, only 2 adverse drug reactions were reported.

Based on the considerations laid down above, Citrus/Cydonia comp. may be an effective and safe treatment for seasonal allergic rhinitis. Due to its selective effect on immunological pathways, Citrus/Cydonia comp. might restore the disturbed immune state of rhinitis patients by modulation of the Th1-Th2 balance.

Study objective

Several observational studies have shown that Citrus/Cydonia comp. might be an effective treatment option for patients suffering from seasonal allergic rhinitis. In these studies Citrus/Cydonia comp. was either administered subcutaneously or given as a nasal spray. In the present SuNa Hay Fever Pilot Study we will compare the efficacy and safety of subcutaneous versus nasal spray administration of Citrus/Cydonia comp. in patients with seasonal allergic rhinitis by specifically investigating which route of administration is more effective in the differentiation and inductions of (regulatory) T-cells. The primary outcome variables are changes in immunological parameters such as IL-10, IL-12 and IL-5 at week 6, as studied in PMBCs isolated from the blood of the patients, respectively. Further objectives are to investigate the influence of Citrus/Cydonia comp. subcutaneous injections versus nasal spray on the change in clinical symptoms by means of nasal and non-nasal symptom scores. The safety and tolerability of Citrus/Cydonia comp. injections and nasal spray will be investigated by determining adverse events surveillance.

Study design

A randomised, comparative clinical trial with two parallel groups

Intervention

After a 2-week run in period the patients will be randomised to a 6 weeks treatment period.
Treatment group A:
Subcutaneous injections:
twice a week, 1% Citrus/Cydonia comp.
Treatment group B:
Nasal spray:
1-2 sprays of Citrus/Cydonia comp. in each nostril, 4 times a day

Study burden and risks

- All patients will have to complete 2 times a day a questionnaire and will have taken two blood samples.
- The patients that participate in the research group will receive 2 times a week Citrus/ Cydonia comp. injections subcutaneous administrated or 4 times a day Gencydo nasal spray.
- In the 2 weeks before onset of the study, participants cannot use regular hay fever medication which will result in an increase of hay fever symptoms.

The risks are the common small risks of subcutaneous administration and venous blood samples.

There are no known side effects of the subcutaneous administration of Citrus/ Cydonia comp. other than local and small pain symptoms that last for only a short amount of time. Also known to mild adverse events have been reported for Gencydo nasal spray (dry and irritated nasal mucosa).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria
1. Written informed consent
2. Age >= 18 and < 60 years
3. Seasonal allergic rhinitis:
a. Duration of at least 2 years
b. High RAST grass pollen (>= 2)

c. Suffering from the following symptoms: sneezing, itching (nose and eyes) and watery nasal discharge,
d. Severity score of at least two of the three symptoms >= 2; ranging from 0 = not present to 3= severe, as measured with the the Disease-specific severity Score questionnaire - nasal symptoms
e. The necessity to use antihistamines and/or corticosteroids for treatment of symptoms for previous (at least two) years.

Exclusion criteria

1. Chronic inflammatory autoimmune disease such as Type I - Diabetes Mellitus, Rheumatoid Arthritis, Multiple Sclerosis, Psoriasis or Crohn*s disease
2. Allergic (hypersensitive) to one of the constituents of Citrus/Cydonia comp.
3. Pharmacological treatment of allergic rhinitis or use of other preparations containing Citrus and or Cydonia extracts within the last two weeks prior to enrolment into the study
4. Use of cromoglycates in the last month before study onset
5. Concomitant pharmacological treatment indicated for seasonal allergic rhinitis such as antihistamines, corticosteroids or other preparations
6. Participation in a further clinical trial at the same time or within the previous 4 weeks prior to enrolment into this study
7. Pregnancy or lactation
8. Severe internal or systemic disease (e.g. cardiac, hepatic, renal diseases)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-05-2007
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Citrus/ Cydonia comp.
Generic name:	Citrus/ Cydonia comp.
Product type:	Medicine
Brand name:	Gencydo nasal spray
Generic name:	Citrus/ Cydonia comp. nasal spray

Ethics review

Approved WMO Date:	09-04-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-04-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-05-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-06-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-06-2009

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2007-001285-32-NL
CCMO	NL16936.040.07