The CiSAR Study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27660

Source
Nationaal Trial Register

Health condition

grass pollenseasonal allergic rhinitis
Hooikoorts (graspollen)

Sponsors and support

Primary sponsor: Lectoraat Antroposofische Gezondheidszorg

Hogeschool Leiden
Cluster Zorg
Zernikedreef 11 (D0.036)
Postbus 382, 2300 AJ LEIDEN
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Source(s) of monetary or material Support: Weleda AG

Intervention

Outcome measures

Primary outcome

Days with symptom control” defined by:
a) A Total Symptom Score of ≤ 8 (while exposed to a mean pollen count of 20-50) or ≤ 12

(while exposed to a mean pollen count of > 50)
and
b) No use of rescue medication
in the verum groups compared to the placebo group in the last two weeks of treatment

Secondary outcome

1. Total use of rescue medication throughout the whole treatment period.
2. Number of drop outs between verum groups and placebo group.
3. Safety: Adverse events.
4. “Days with symptom control” in the verum groups compared to the placebo group in the third and fourth weeks of treatment or the fifth and sixth weeks of treatment in case of extended treatment.

Study description

Study objective

Hypothesis 1: There is a difference of at least 30% in mean “days with symptom control” between the Citrus/Cydonia comp. 1% verum group compared to the placebo group in the last two weeks of treatment in favour of Citrus/Cydonia comp. 1% solution for injection.
Hypothesis 2: There is a difference of at least 15% in mean “days with symptom control” between the Citrus/Cydonia comp. 1-5% verum group compared to the Citrus/Cydonia comp. 1% verum group in the last two weeks of treatment in favour of Citrus/Cydonia comp. 1-5% solution for injection.
Hypothesis 3: There is a statistically significant difference in the use of rescue medication during the whole treatment period between the verum and the placebo group in favour of Citrus/Cydonia comp. 1% solution for injection and Citrus/Cydonia comp. 1-5% solution for injection.
Hypothesis 4: There is a statistically significant difference in the number of drop outs between the verum and the placebo group in favour of Citrus/Cydonia comp. 1% solution for injection and Citrus/Cydonia comp. 1-5% solution for injection.

Study design

Visit 1 (week -3/-2/day -3): Enrolment, duration wash-out depending on previously used medication
Visit 2 (week 0/day 0): Baseline scores, intervention
Visit 3 (week 3 (& week5*): Telephone check
Visit 4 (week 6/ week 8*): Symptom scores

Intervention

Subcutaneous injections

Contacts

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Eligibility criteria

Inclusion criteria

1. Written informed consent
2. Age ≥ 18 and < 60 years
3. Seasonal allergic rhinitis:
- Duration of respective complaints at least 2 years
- Suffering from the following nasal symptoms: sneezing, itching nose, nasal obstruction and watery nasal discharge
- Severity score of at least two of the four nasal symptoms ≥ 2 (ranging from 0 = not present to 3= severe)
- Suffering from the following non-nasal symptoms: itchy/burning eyes, watery eyes, redness of eyes and itching ears/throat
- Severity score of at least two of the four non-nasal symptoms ≥ 2 (ranging from 0 = not present to 3 = severe)
- The necessity to use antihistamines and/or corticosteroids for treatment of symptoms for at least two previous years
- Average Total Symptom Score in the wash-out period ≥ 9 on days with a pollen count > 20 or use of rescue medication on days with a pollen count > 20.

Exclusion criteria

1. Chronic inflammatory autoimmune disease such as Diabetes Mellitus type 1, Rheumatoid Arthritis, Multiple Sclerosis, Psoriasis or Crohn’s disease
2. Known hypersensitivity to one of the constituents of Citrus/Cydonia comp.
3. Participation in a further clinical trial at the same time or within the previous 4 weeks prior to enrolment into this study
4. Previous use of medicinal products containing Citrus and/or Cydonia
5. Pregnancy or lactation
6. Severe internal or systemic disease (e.g. cardiac, hepatic, renal diseases)
7. A known history of drug, alcohol and/or medication dependence or addiction
8. Immunotherapy in the last two years
9. Use of cromoglycates
10. Other allergies (non seasonal allergies)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2014
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-03-2014

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40456
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4220
NTR-old	NTR4459
CCMO	NL47143.028.13
OMON	NL-OMON40456

Study results