The CiSAR Study

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27660

Bron
Nationaal Trial Register

Aandoening

grass pollenseasonal allergic rhinitis
Hooikoorts (graspollen)

Ondersteuning

Primaire sponsor: Lectoraat Antroposofische Gezondheidszorg

Hogeschool Leiden
Cluster Zorg
Zernikedreef 11 (D0.036)
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M: +31 6 468 468 04
Overige ondersteuning: Weleda AG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Subcutaneous injections

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-03-2014

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40456
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten