Sublingual immunotherapy with house dust mite allergen in children with allergic rhinitis: randomised double-blind placebo-controlled trial.

No registrations found.

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

Summary

ID

NL-OMON28314

Source
NTR

Brief title
STARDROP II

Health condition

allergic rhinitis related to house dust mite allergy

Sponsors and support

Primary sponsor: ARTU Biologicals Europe BV
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Mean rhinitis symptom score in September-December after 2 years of SLIT / placebo.

Secondary outcome

(all in September-December after 2 years of SLIT/placebo, except last outcome below)

1. Proportion of symptomfree days;

2. Proportion of days without recue medication;

3. Mean eye symptom score;

4. Total symptom score;

5. Rhintis specific quality of life questionnaire (PARQLQ);

6. Overall assessment of perceived benefit by child and parent over whole period.

Study description

Background summary

N/A

Study objective

Null hypothesis: sublingual immunotherapy with house dust mite allergen is as effective as placebo on daily symptoms in children with allergic rhinitis.

Intervention

Sublingual immunotherapy (SLIT) with house dust mite allergen during 24-26 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age: 6-18 years;

2. History of allergic rhinitis for at least one year;

3. Positive RAST for house dust mite allergy (¡Ý2+);

4. No use of nasal steroids in month before start of baseline measurements;

5. Symptom score of at least 4/12 (four nasal symptoms with scores ranging 0-3);

6. Informed consent.

Exclusion criteria

1. Severe asthma;

2. Allergic sensitivity to pets, in case these are present in the family home;

3. Planned surgery of nasal cavity in the course of the study;

4. Having received immunotherapy in past three years;

5. Contraindications to sublingual immunotherapy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-09-2005
Enrollment:	256
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-09-2005
Application type:	First submission

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
NTR-new	NL346
NTR-old	NTR385

Register	ID
Other	: N/A
ISRCTN	ISRCTN91141483

Study results

Summary results
N/A