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

Submission date 19/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/12/2005	**Overall study status** Completed	
Last Edited 27/10/2022	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR385

Study information

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

Acronym
STARDROP II

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

Please note that as of 03/07/2008 more details on the sources of funding have been added to this record. This can be seen below in the sources of funding section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Review Board of Erasmus Medical Centre on the 13th September 2005.

Study design
Randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Rhinitis, allergy, house dust mite

Interventions
Sublingual immunotherapy (SLIT) with house dust mite allergen for 24 - 26 months.
Control: placebo.

Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
All in September - December after 2 years of SLIT/placebo, except last outcome below:
1. Proportion of symptom free days
2. Proportion of days without rescue medication
3. Mean eye symptom score
4. Total symptom score
5. Rhinitis specific quality of life questionnaire (PARQLQ)
6. Overall assessment of perceived benefit by child and parent over whole period

Overall study start date
19/09/2005

Completion date
31/12/2008

Eligibility

Key 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 (Y2+)
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

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Not Specified

Target number of participants
256

Total final enrolment
251

Key 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

Date of first enrolment
19/09/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Artu Biologicals Europe B.V. (Netherlands)

Sponsor details
Vijzelweg 11
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Sponsor type
Industry

ROR
https://ror.org/022w0b336

Funder(s)

Funder type
Industry

Funder Name
Added on 03/07/2008:

Funder Name
Artu Biologicals Europe B.V. (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/10/2008		Yes	No
Results article		01/03/2012	27/10/2022	Yes	No