

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 ☒ Protocol
Registration date 19/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/10/2022	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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.

Primary study design

Interventional

Study design

Randomised double blind placebo controlled parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Years

Upper age limit

18 Years

Sex

Not Specified

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)

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

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?
Results article		01/03/2012	27/10/2022	Yes	No
Protocol article	protocol	20/10/2008		Yes	No