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The effect of birch pollen immunotherapy on hazelnut allergy.

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/11/2008	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr K.A.B.M. Peeters

Contact details
University Medical Centre Utrecht
Department of Dermatology/Allergology
P.O. Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 250 7388
K.A.B.M.Peeters@umcutrecht.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR172

Study information

Scientific Title
The effect of birch pollen immunotherapy on hazelnut allergy evaluated by DBPCFC with hazelnut

Study objectives
The severity of hazelnut allergy will decrease as an additional effect by birch pollen immunotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, double-blind, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pollen/hazelnut allergy

Interventions
Immunotherapy with birch pollen extract.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Birch pollen extract

Primary outcome measure
DBPCFC with hazelnut before immunotherapy with birch pollen and after 1 year.

Secondary outcome measures
1. Skin prick tests
2. Serological analyses

Overall study start date
01/04/2004

Completion date
01/11/2005

Eligibility

Key inclusion criteria
Patients greater than 18 years with birch pollen allergy and hazelnut allergy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
19

Key exclusion criteria
1. Pregnancy
2. Significant concurrent disease
3. Instable asthma and oral medication with corticosteroids or beta-blocking agents

Date of first enrolment
01/04/2004

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
Netherlands

Study participating centre

University Medical Centre Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

Sponsor details
Department of Dermatology and Allergology
P.O. Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 250 7388
info@umcutrecht.nl

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Industry

Funder Name
ALK-Abello BV (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration