ISRCTN42318360 https://doi.org/10.1186/ISRCTN42318360

The efficacy of the combination of allergen vaccination and vitamin D3 in the reduction of allergen-specific nasal responses. A placebo controlled trial.

Submission date 09/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 25/08/2009	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

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
NTR522; PG/0020 (MEC 05/204)

Study information

Scientific Title

Acronym
VITAL

Study objectives
Addition of subcutaneous vitamin D3 to subcutaneous allergen vaccination offers a superior protection to allergen-induced inflammation and obstruction, in comparison to allergen vaccination alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre 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

Interventions
Subcuteneous injections with:
1. Purethal grass pollen per protocol
2. Calcitriol per protocol
3. Histamine (placebo for Purethal)
4. 0.9% NaCl (placebo for Calcitriol)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Early reduction of allergen induced inflammation (9 weeks) measured as symptoms of sneezing, rhinorrhoea and nasal blockage after an individually standardised allergen dose (10 x and 100 x the initial threshold provocation dose) in the first hour after each allergen provocation.

Secondary outcome measures
1. Airway patency measured by PNIF during the first hour and the 24 hours after allergen challenge
2. Nasal symptom score for 24 hours after nasal allergen challenge
3. ECP/albumin ratio and cytokines (IL5, IL10) in nasal lavage
4. Clinical index score (CIS) during the grass-pollen season 2006

Overall study start date
01/12/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Patients with rhinoconjunctivitis with or without mild asthma for at least 2 years. Their allergic symptoms should be related to the grass-pollen season.
2. A positive skin prick test for grass, minimally HEP 1
3. Positive reaction to intranasal challenge with grass-pollen
4. Age between 18 and 65
5. Patients with a written informed consent

Note: Patients with concomitant sensitisation to perennial allergens like house dust mite and pets can be included as long as they do not reveal clinical symptoms or only at very rare occasional exposure. In case of sensitisation to pets, these pets should not be present at home.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Use of corticosteroids (systemic and local) outside grass-pollen season (May-July)
2. Serious immunopathologic diseases or malignancies (including auto-immune diseases, tuberculosis)
3. Severe asthma or emphysema, based on questionnaire; use of inhaled corticosteroids
4. Chronic symptoms related to concomitant sensitisation to other perennial allergens like pets or mites
5. Symptomatic coronary heart diseases or severe (even under treatment) arterial hypertension
6. Diseases with a contra-indication for the use of adrenaline
7. Severe kidney disease
8. Treatment with beta-blockers or ACE inhibitors or immunosuppressive drugs
9. Severe atopic dermatitis
10. Immunotherapy (including sublingual) treatment with grass-pollen within the last 5 years
11. Pregnancy, lactation or inadequate contraceptive measures
12 Alcohol or drug abuse
13. Lack of co-operation or severe psychological disorders

Date of first enrolment
01/12/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Almere
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
MedAmon B.V. i.o. (Netherlands)

Funder Name
HALMON Laboratoria Beheer 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

IPD sharing plan summary
Not provided at time of registration