

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/08/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof W.J. Fokkens

Contact details

Academic Medical Center
Department of Otorhinolaryngology
Room A2-234
P.O. Box 22660
Almere
Netherlands
1100 DD
+31 (0)20 5663789
W.J.Fokkens@amc.nl

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Multicentre randomised double blind placebo controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rhinitis

Interventions

Subcutaneous 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration