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The effects of low dose 1,25-dihydroxyvitamin D3 on the polarising of cellular immune reactivity towards type two immunity

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 06/09/2011	**Condition category** Haematological Disorders	

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

2006/160

Study information

Scientific Title

Study objectives
Short term oral low dose 1,25-dihydroxyvitamin D3 (1,25(OH)2D3) in man will increase type-two and decrease type-one cellular immune reactivity without affecting serum calcium levels. Hereby, the potential usage of 1,25(OH)2D3 for immuno-therapeutical approaches will be investigated.

Ethics approval required
Old ethics approval format

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

Study design
Randomised, placebo controlled, parallel group, double blinded 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
Auto-immune diseases

Interventions
Twelve volunteers will receive ten capsules of 0.5 µg calcitriol, the other twelve volunteers will receive ten capsules of placebo. They have to take the medication twice a day during five days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Calcitriol

Primary outcome measure
We expect the serum level of 1,25(OH)2D3 to rise and to induce the activity of T lymphocytes and the dendritic cells which regulate the immunity and reduce the activity of type one T lymphocytes involved in auto-immune diseases. Their activity will be measured by the decrease of interferon gamma production.

Secondary outcome measures
We expect the type one cytokines to be decreased and the type two cytokines to be upregulated.

Overall study start date
15/11/2006

Completion date
15/03/2007

Eligibility

Key inclusion criteria
1. Written informed consent
2. Women, aged 20 to 30 years
3. Use of oral contraception with estrogen and progestin
4. Apparently healthy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
24

Key exclusion criteria
1. Men
2. Pregnancy
3. Smoking
4. Alcohol abuse: more than 3 Units/day
5. Use of drugs, except for incidental analgesic agents
6. Use of diuretic medication or corticosteroids
7. Auto immune diseases
8. Renal impairment (serum creatinine more than 150 µmol/l)
9. Malignant disease
10. Kidney-stones (also when this occurs in the family), urinary tract infections
11. Infectious diseases

12. Use of antibiotics
13. Use of any medication that influence T-lymphocytes or vitamin D metabolism
14. Disease or use of any medication known to affect Ca metabolism or skeletal physiology
15. Serious mental impairment i.e. preventing to understand the study protocol/aim

Date of first enrolment
15/11/2006

Date of final enrolment
15/03/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Centre
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
VU University Medical Center (The Netherlands)

Sponsor details
Department of Endocrinology
De Boelelaan 1118
Amsterdam
Netherlands
1081 HV

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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