

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

<b>Submission date</b> 28/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/09/2011	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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## Additional identifiers

**Protocol serial number**  
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

**Primary study design**

Interventional

**Study design**

Randomised, placebo controlled, parallel group, double blinded trial

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s)**

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

**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

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

Female

### 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  $\mu\text{mol/l}$ )
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)

**ROR**  
<https://ror.org/00q6h8f30>

## **Funder(s)**

**Funder type**  
Not defined

**Funder Name**  
Not provided at time of registration

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration