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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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