The effects of low dose 1,25-dihydroxyvitamin D3 on the polarising of cellular immune reactivity towards type 2 immunity.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29360

Source
NTR

Brief title
N/A

Health condition

auto-immune diseases

Sponsors and support

Primary sponsor: dr. E.M.W. Eekhoff
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Source(s) of monetary or material Support: Medicina Interna

Intervention

Outcome measures

Primary outcome

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 1 T lymphocytes involved in auto-immune diseases. Their activity will be measured by the decrease of interferon gamma production.

Secondary outcome

We expect the type 1 cytokines to be decreased and the type 2 cytokines to be upregulated.

Study description

Background summary

N/A

Study objective

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

Study design

N/A

Intervention

Twelve volunteers will receive 10 capsules of 0,5 µg calcitriol, the other twelve volunteers will receive 10 capsules placebo. They have to take the medication twice a day during 5 days.

Contacts

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Eligibility criteria

Inclusion criteria

1. Written informed consent;

2. women, aged 20-30 years;

3. use of oral contraception with estrogen and progestin;

4. apparently health.

Exclusion criteria

1. Men;

2. pregnancy;

3. smoking;

4. alcohol abuse: > 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 >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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2006
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	10-08-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL784
NTR-old	NTR796
Other	MEC VU : 2006/160
ISRCTN	ISRCTN12365646

Study results

Summary results
N/A