ISRCTN65263333 https://doi.org/10.1186/ISRCTN65263333

Serum Provitamin D kinetic upon oral intake

Submission date	Recruitment status	[_] Prospectively registered
21/11/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/04/2022	Other	

Plain English summary of protocol

Background and study aims:
Vitamin D deficiency is associated with allergy and autoimmune diseases. However, long-term treatment of patients with allergies with vitamin D (calcitriol) is limited, as large doses can be toxic. Activated immune cells can, however, create their own calcitriol. We want to investigate how we can target these cells to stimulate calcitriol production.

Who can participate?
Healthy individuals and patients with autoimmunity or allergy between 18-60 years.

What does the study involve?
One groups will receive vitamin D, and the other group will not. A control cohort will not receive vitamin D. The group that does, will have monthly increases in doses of daily vitamin D intake. Blood samples will be take twice a month to assess each individuals vitamin D status and to monitor immune cells.

What are the possible benefits and risks of participating?
Participants will be supporting academic medical research. Risks of taking part in the study include vitamin D intoxication which can cause nausea and weakness. There is also risk of bruising after blood samples are taken, however this should be minimised as only experienced staff will be taking samples.

Where is the study run from?
Department of Dermatology, Venereology and Allergology at the Charité in Berlin, Germany

When is the study starting and how long is it expected to run for?
Recruitment for the study started in December 2009 and ended in December 2010. The study period was for 4 months, and ended in May 2011.

Who is funding the study?
German Research Foundation [Deutsche Forschungsgemeinschaft (DFG)] ref: SFB650-TP5.

Who is the main contact?
Prof Margitta Worm
margitta.worm@charite.de

Contact information

Type(s)
Scientific

Contact name
Dr Guido Heine

Contact details
Department of Dermatology & Allergy
Charité - Universitätsmedizin Berlin
Chariteplatz 1
Berlin
Germany
10117

Additional identifiers

Protocol serial number
Prokin D

Study information

Scientific Title
Serum Provitamin D kinetic upon oral intake: an open label dose escalation study

Acronym
ProKin D

Study objectives
We suppose that serum 25-hydroxyvitamin D concentrations will be reached exceeding 100 nmol /L upon vitamin D intake in increasing dosages and maintained >50 nmol/L over 3 months after termination of vitamin D intake.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charité, Universitätsmedizin Berlin (Germany), 19 November 2008, ref: EA1-151-08
Amendments approved on 10 May 2010

Study design
Open label dose-escalation trial

Primary study design
Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied
Vitamin D supplementation

Interventions
1. Vitamin D groups monthly increasing doses of vitamin D, in detail 2000 I.U. Daily followed by 4000 I.U. and 8000 I.U in the presence of 1 mg calcium daily
2. Controls: none

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin D

Primary outcome(s)
Achievement of serum 25-hydroxyvitamin D concentrations above 100 nM on screening visits and 4 monthly study visits

Key secondary outcome(s))
1. Serum concentrations of calcium, phosphorus, creatinine
2. Monitor activation and phenotype of peripheral lymphocytes

Assesed on screening visits and 4 monthly study visits

Completion date
01/04/2010

Eligibility

Key inclusion criteria
1. Healthy individuals, patients with type I allergy
2. Age 18-60 years
3. No excessive tanning in last 4 weeks
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
60 years

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Simultaneous participation in an other study
2. Expected incompliance
3. Pregnancy, lactation
4. Disease of the cardiovascular system, kidneys, thyroid gland
5. Malignant diseases
6. Malabsorbtion
7. Chronic infections
8. Planned exzessive tanning during the investigation time

Date of first enrolment
10/12/2008

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Germany

Study participating centre
Department of Dermatology & Allergy
Berlin
Germany
10117

Sponsor information

Organisation
Charité - Universitätsmedizin Berlin (Germany)

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Government

Funder Name
Germn Research Foundation [Deutsche Forschungsgemeinschaft (DFG)] (Germany) ref: SFB650-TP5

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/01/2017	14/04/2022	Yes	No