

# Serum Provitamin D kinetic upon oral intake

<b>Submission date</b> 21/11/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/12/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/04/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Non randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

Achievement of serum 25-hydroxyvitamin D concentrations above 100 nM on screening visits and 4 monthly study visits

**Secondary outcome measures**

1. Serum concentrations of calcium, phosphorus, creatinine
2. Monitor activation and phenotype of peripheral lymphocytes

Assesed on screening visits and 4 monthly study visits

**Overall study start date**

10/12/2008

**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

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

60 Years

## Sex

Both

## Target number of participants

48

## 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. Malabsorption
7. Chronic infections
8. Planned excessive 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)

**Sponsor details**  
c/o Margitta Worm  
Klinik für Dermatologie, Venerologie und Allergologie  
Allergie-Centrum-Charité, CCM  
Charitéplatz 1  
Berlin  
Germany  
10117

**Sponsor type**  
University/education

**Website**  
<http://www.charite.de/en/charite/>

**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

**Publication and dissemination plan**

Not provided at time of registration

### Intention to publish date

### 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?
<a href="#">Results article</a>		23/01/2017	14/04/2022	Yes	No