

# Studying the effect of vitamin D supplementation in human immunodeficiency virus (HIV) patients who have experienced loss of bone mineral density over time

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
02/09/2011	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
17/11/2011	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
21/12/2017	Infections and Infestations	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Barry Peters

### Contact details

Harrison Wing  
2nd Floor Lambeth Wing  
St. Thomas' Hospital  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

## Additional identifiers

### Protocol serial number

PB002

## Study information

**Scientific Title**

A prospective study of loss of bone mineral density in patients with HIV over time: implications for clinical practice and therapeutic options - Vitamin D sub study

**Study objectives**

To explore the effects and potential benefits of high doses of vitamin D supplementation on various parameters of the immune system

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee London - Westminster, approval pending

**Study design**

Phase IV open label study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Human immunodeficiency virus (HIV)

**Interventions**

There are no treatment arms, there are 3 cohorts: HIV positive (on treatment), HIV Positive (Naive), HIV Negative. All are given 200,000 units stat colecalciferol at baseline and followed up over a 12 week period by doing physical exam, blood samples and urine samples.

**Intervention Type**

Supplement

**Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

Colecalciferol (Vitamin D)

**Primary outcome(s)**

1. Efficacy: level in serum vitamin D levels to be above those at baseline

2. Safety:

2.1. Routine: serum renal, liver, bone, glucose, Full Blood Count (FBC)

2.2. Vital signs including blood pressure (BP), pulse, temperature

2.3. Renal: urine dipstick (blood, protein, leukocytes, glucose), urine protein/creatinine (PCR)

2.4. Bone biochemistry to include: Vitamin D, parathyroid hormone, alkaline phosphatase (ALP)

Samples obtained at baseline, week 4 and week 12

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

01/03/2012

## Eligibility

**Key inclusion criteria**

1. Aged between 18 years and 45 years , males and females
2. Documented Positive HIV-1 antibody test and either stable on highly active antiretroviral therapy (HAART) as defined by undetectable viral load and on the same regimen for more than 6 months or treatment naive (HIV+ cohort only) (n=32)
3. Presumed HIV negative C (HIV negative cohort only) (n=16)
4. Ability to give informed consent
5. Willing to use barrier method contraception (condoms) for the duration of the trial
6. Documented Vitamin D deficiency (less than 50 nmol/L within 6 months of screening)
7. Not currently taking Vitamin D supplements, or have taken any Vitamin D supplements within 4 weeks of screening

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Pregnancy or breast feeding
2. Patient unlikely to comply with protocol
3. Received vitamin D supplementation within the previous 4 weeks
4. Documented history of renal impairment
5. Any chronic inflammatory condition
6. Documented Hepatitis B or C
7. Documented soya or peanut allergy or hypersensitivity to any of the constituents of Dekristol®
8. Hypercalcaemia or hypercalciuria
9. Pseudohypoparathyroidism

**Date of first enrolment**

01/11/2011

**Date of final enrolment**

01/03/2012

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

St. Thomas' Hospital

London

United Kingdom

SE1 7EH

## Sponsor information

### Organisation

King's College London - Guy's and St Thomas' NHS Foundation Trust (UK)

### ROR

<https://ror.org/00j161312>

## Funder(s)

### Funder type

Industry

### Funder Name

ViiV Pharmaceuticals (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

### 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="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes