

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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

Primary study design

Interventional

Study design

Phase IV open label study

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 dipstix (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