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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 [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/11/2011	**Overall study status** Completed	
Last Edited 21/12/2017	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact HW.Research@gstt.nhs.uk to request a patient information sheet

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 measure
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 biochemisty to include: Vitamin D, parathyroid hormone, alkaline phosphatase (ALP)
Samples obtained at baseline, week 4 and week 12

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

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
England

United Kingdom

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)

Sponsor details
Joint Clinical Trials Office
16th Floor Tower Wing
Guy's Hospital
Great Maze Pond
London

England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.kcl.ac.uk/nursing/partners/nhs/gstt.aspx

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
ViiV Pharmaceuticals (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration