Clinical trial results:
Effects of Vitamin D supplementation on Vitamin D levels and immune activation in HIV infected individuals on antiretroviral therapy-A pilot study.

Summary

EudraCT number	2010-022775-57
Trial protocol	GB
Global end of trial date	10 April 2014

Results information

Result version number	v1 (current)
This version publication date	14 October 2018
First version publication date	14 October 2018
Summary attachment (see zip file)	Publication (no-benefit-of-standard-vitamin-dcalcium-supplementation-in-hivinfectedindividuals-23.pdf) FINAL STUDY REPORT (acsharp_14-10-2015_14-46-09.pdf)

Trial information

Trial identification

Sponsor protocol code	JF002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Guy's and St Thomas' NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE19RT
Public contact	Dr Julie Fox, Guy's and St Thomas' NHS Foundation Trust, 0044 0207188 7188, julie.fox@kcl.ac.uk
Scientific contact	Dr Julie Fox, Guy's and St Thomas' NHS Foundation Trust, 0044 0207188 7188, julie.fox@kcl.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 April 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 April 2014
Global end of trial reached?	Yes
Global end of trial date	10 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Investigate the role vitamin D supplementation on restoring vitamin D levels in HIV infected individuals on antiretroviral therapy.

Protection of trial subjects:

Safety blood tests (FBC, Urea and electrolytes and liver function tests) and adherence review are incorporated into the visit schedule.

Background therapy:

All participants must be receiving antiretroviral therapy

Evidence for comparator: -

Actual start date of recruitment	22 November 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from one clinical site in London UK between November 2011 and April 2014.

Pre-assignment

Screening details:

Having given consent, participants will undergo screening assessments to determine whether they are eligible to participate in the study according to the inclusion/exclusion criteria. The following evaluations will be performed during Screening: Review of inclusion/exclusion criteria PIS and Written Informed Consent Conmed review Directed Physical

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Participants will be randomised on a 1:1 basis with randomisation/allocation to study arm

Arms

Are arms mutually exclusive?	Yes
Arm title	Vit D

Arm description:

At baseline participants will be randomized to receive vitamin D supplements for 48w.

Arm type	Experimental
Investigational medicinal product name	Adcal D3 Lemon Chewable Tablets
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Adcal D3® lemon flavoured chewable tablet: 2 tablets daily

Arm title	No Vit D

Arm description:

Standard care with no added intervention

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Vit D	No Vit D
Started	15	15
Completed	15	14
Not completed	0	1
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	30	30	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	44		
full range (min-max)	30 to 59	-	
Gender categorical Units: Subjects			
Female	5	5	
Male	25	25	

End points

End points reporting groups

Reporting group title	Vit D
Reporting group description:	
At baseline participants will be randomized to receive vitamin D supplements for 48w.	
Reporting group title	No Vit D
Reporting group description:	
Standard care with no added intervention	

Primary: Clinical Endpoint

End point title	Clinical Endpoint[1]
End point description:	
The primary outcome is the mean change in 25 (OH) D level at 48 weeks from baseline in each arm	
End point type	Primary
End point timeframe:	
48 weeks from baseline	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see attached report for results and statistical analysis.

End point values	Vit D	No Vit D		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	14		
Units: ug/L				
arithmetic mean (standard error)	-5.2 (± 0)	0.2 (± 0)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Duration of trial	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1
Reporting groups	
Reporting group title	Vit D
Reporting group description: Intervention of Vitamin D	
Reporting group title	No Vit D
Reporting group description: Control group without intervention	

Serious adverse events	Vit D	No Vit D	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Immune system disorders			
Initiation of Duranavir/Ritonavir	Additional description: Overnight hospital admission for initiation of Duranavir/Ritonavir treatment		
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Fracture left Mandibular condyle			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Vit D	No Vit D	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 15 (93.33%)	14 / 15 (93.33%)	
Investigations			
Increased glucose levels	Additional description: Increased glucose levels secondary to Duranavir		
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Left shoulder operation			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Burning sensation /numbness knee and thigh			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Cluster headache			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	
occurrences (all)	2	0	
Migraine			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Numbness of fingers			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Sciatica			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Accidental exposure			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Fever			

subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Loss of appetite			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Skin rash and cellulitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Cervical /sub mandibular lymph node inflammation			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Hayfever			
subjects affected / exposed	2 / 15 (13.33%)	1 / 15 (6.67%)	
occurrences (all)	2	1	
Eye disorders			
Blurred Vision			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Constipation, Jaundice, vomiting			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Common cold			
subjects affected / exposed	1 / 15 (6.67%)	2 / 15 (13.33%)	
occurrences (all)	1	2	
Coryzal runny nose			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Coryzal symptoms			
subjects affected / exposed	3 / 15 (20.00%)	2 / 15 (13.33%)	
occurrences (all)	3	2	

Cough with frothy white sputum			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Dry cough			
subjects affected / exposed	2 / 15 (13.33%)	1 / 15 (6.67%)	
occurrences (all)	2	1	
Dry cough at night			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Head cold			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
LRTI and flu like symptoms			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Right ring finger rash			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Skin rash			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Osteoporosis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Right calf pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Painful ankle			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Painful ankles			

subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Painful shoulder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Athletes foot			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Candida Balantis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Ear Infection			
subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	
occurrences (all)	2	0	
Eye Infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Mouth Abscess			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Vaginal Thrush			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Anaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Hypercholesterolaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 December 2011	Changes to the inclusion/exclusion criteria. The change of visit 5 from a clinic visit to a telephone visit. This is to more accurately reflect current medical practice for visit schedule. The lab test for CRP has been removed throughout the protocol and the method of randomisation has been changed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported