



## 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
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##### 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:

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**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:

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**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:

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**Population of trial subjects**

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**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:

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**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
<b>Arm title</b>	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

<b>Arm title</b>	No Vit D
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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 <sup>[1]</sup>
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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.1
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### Reporting groups

Reporting group title	Vit D
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Reporting group description:

Intervention of Vitamin D

Reporting group title	No Vit D
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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 occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	
Loss of appetite subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	
Immune system disorders Skin rash and cellulitis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	
Cervical /sub mandibular lymph node inflammation subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	
Hayfever subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	1 / 15 (6.67%) 1	
Eye disorders Blurred Vision subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	
Gastrointestinal disorders Constipation, Jaundice, vomiting subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1	
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	
Common cold subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	2 / 15 (13.33%) 2	
Coryzal runny nose subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	
Coryzal symptoms subjects affected / exposed occurrences (all)	3 / 15 (20.00%) 3	2 / 15 (13.33%) 2	

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

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

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported