Clinical trial results:
Can Vitamin D Replacement Reduce Insulin resistance In South Asians with Vitamin D Deficiency?

Summary

EudraCT number	2010-024213-31
Trial protocol	GB
Global end of trial date	08 January 2014

Results information

Result version number	v1 (current)
This version publication date	01 July 2020
First version publication date	01 July 2020
Summary attachment (see zip file)	File note (Early Termination file note.pdf)

Trial information

Trial identification

Sponsor protocol code	UNOLE0166

Additional study identifiers

ISRCTN number	ISRCTN18522562
ClinicalTrials.gov id (NCT number)	NCT01385345
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Leicester
Sponsor organisation address	Research Governance Office, Academic Department, Leicester General Hospital, Leicester, United Kingdom, LE5 4PW
Public contact	Professor Melanie Davies, University of Leicester, +44 01162586481, melanie.davies@uhl-tr.nhs.uk
Scientific contact	Professor Melanie Davies, University of Leicester, +44 01162586481, melanie.davies@uhl-tr.nhs.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	08 January 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 January 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The principal objective of this study is to assess whether giving 6 months of high dose Vitamin D3 (200,000 units or 100,000 units once every six to eight weeks) oral liquid drops together with daily maintenance Vitamin D3 1000 units tablets in south Asians with low vitamin D (25OH vitamin D3 <25nmol/l) improves markers of insulin function (specifically a marker known as HOMA1-IR, by greater than 0.36 units) compared to south Asians with low Vitamin D levels who take just maintenance 1000 units Vitamin D3 per day.

Protection of trial subjects:

N/A - trial ended prematurely

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Only 3 participants were randomized prior to the study being terminated. No data analysis was carried out (due to lack of data) and there have been no study publications. MHRA confirmed that the study is exempt to posting results on 24.05.2019

Pre-assignment

Screening details:

N/A

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:

N/A

Arms

Arm title	Vitamin D3

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Vitamin D3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral drops, solution
Routes of administration	Oral use

Dosage and administration details:

Dosage would have been 100,000 units

Number of subjects in period 1	Vitamin D3
Started	99999
Completed	99999

Baseline characteristics

End points

End points reporting groups

Reporting group title	Vitamin D3

Reporting group description: -

Primary: Reduction in insulin resistance

End point title	Reduction in insulin resistance[1]

End point description:

End point type	Primary

End point timeframe:

N/A

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: Only 3 participants were randomised prior to the study being terminated. Insufficient data was generated and therefore no analysis has been performed. No results are available for this study.

End point values	Vitamin D3			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: n/a	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
All adverse events occurring during the course of study were to be collected.	
Adverse event reporting additional description:	
N/A	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Only 3 participants were randomised prior to the study being terminated. No SAEs were reported prior to termination of the study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Only 3 participants were randomized prior to the study being terminated. No data analysis was carried out (due to lack of data) and there have been no study publications. MHRA confirmed that the study is exempt to posting results on 24.05.2019.

Notes: