Clinical trial results:
Vit-D in CRC - A Randomised Double Blind Placebo-Controlled Clinical Trial Of a Single Oral Cholecalciferol Treatment Against Surrogate End Point Biomarkers (SEBs) In Colon Cancer (CRC) Patients

Summary

EudraCT number	2013-001664-34
Trial protocol	GB
Global end of trial date	24 April 2018

Results information

Result version number	v1 (current)
This version publication date	15 August 2019
First version publication date	15 August 2019

Trial information

Trial identification

Sponsor protocol code	12028-FC-SS

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Belfast Health and Social Care Trust
Sponsor organisation address	Grosvenor Road, Belfast, United Kingdom, BT12 6BA
Public contact	Alison Murphy, Belfast Health and Social Care Trust, 44 02890636366, ResearchSponsor@belfasttrust.hscni.net
Scientific contact	Professor Frederick Charles Campbell, Queens University Belfast, 44 02890638468, f.c.campbell@qub.ac.uk
Sponsor organisation name	Queens University Belfast
Sponsor organisation address	University Road, Belfast, United Kingdom, BT7 1NN
Public contact	Louise Dunlop, Queens University Belfast, 44 02890972572, l.dunlop@qub.ac.uk
Scientific contact	Professor Frederick Charles Campbell, Queens University Belfast, 44 02890638468, f.c.campbell@qub.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	29 April 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 April 2017
Global end of trial reached?	Yes
Global end of trial date	24 April 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Objectives: Part A
To ascertain if the proposed dosing regimen of cholecalciferol achieves cancer-suppressive levels of 25(OH)D in Colorectal Cancer (CRC) patients.

To investigate the safety of the cholecalciferol dose in CRC patients.

Protection of trial subjects:

A Data Monitoring and Ethics Committee (DMEC) was appointed. The DMEC's responsibility was to safeguard the interests of the trial participants, in particular with regarding to safety and they advised the Trial Management Group so as to protect the validity and credibility of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 January 2014
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: 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)	16
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

30 patients were enrolled between 10th December 2013 and 20th March 2017. All patients were recruited from 1 site within the United Kingdom.

Pre-assignment

Screening details:

A total of 228 patients were screened for eligibility in accordance with the study inclusion/exclusion criteria. 198 patients were found to be ineligible or declined to participate.

Period 1

Period 1 title	Part A Dose Confirmation (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject, Monitor, Assessor

Blinding implementation details:

Vigantol oil and the placebo oil were packaged and labeled in matching containers by Victoria Pharmaceuticals in Belfast according to the randomisation scheduled. Each bottle was labeled with a unique identifier and upon patient enrolment the medication packs were dispensed in sequential order starting with the lowest number available.

Arms

Are arms mutually exclusive?	Yes
Arm title	Cholecalciferol 300,000 IU

Arm description:

Single dose of 300, 000 IU cholecalciferol

Arm type	Experimental
Investigational medicinal product name	Cholecalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

A single oral dose of cholecalciferol 300,000 IU on the morning of day 1. Participants were given 15 mL Vigantol oil (MERCK; cholecalciferol 20,000 IU/ml) to be taken by mouth after pre-treatment blood sampling. The study drug was taken with a glass of water and witnessed by a member of the research team.

Arm title	Placebo

Arm description:

Single dose of Placebo liquid oil

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

A single oral dose of placebo oil the morning of day 1. Participants were given 15 mL placebo oil, to be taken by mouth after pre-treatment blood sampling. The placebo oil was taken with a glass of water and witnessed by a member of the research team.

Arm title	Cholecalciferol 600,000 IU

Arm description:

Single dose of 600, 000 IU cholecalciferol

Arm type	Increased Cholecalciferol Dose
Investigational medicinal product name	Cholecalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Single oral dose of cholecalciferol 600,000 IU on the morning of day 1. Participants were given 30 mL Vigantol oil (MERCK; cholecalciferol 20,000 IU/ml) to be taken by mouth after pre-treatment blood sampling. The study drug was taken with a glass of water and witnessed by a member of the research team.

Number of subjects in period 1	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU
Started	10	10	10
Completed	10	10	10

Baseline characteristics

Reporting groups	
Reporting group title	Cholecalciferol 300,000 IU
Reporting group description:	
Single dose of 300, 000 IU cholecalciferol	
Reporting group title	Placebo
Reporting group description:	
Single dose of Placebo liquid oil	
Reporting group title	Cholecalciferol 600,000 IU
Reporting group description:	
Single dose of 600, 000 IU cholecalciferol	

Reporting group values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU
Number of subjects	10	10	10
Age categorical			
Units: Subjects			
Adults (18-64 years)	8	6	2
From 65-84 years	2	4	8
Age continuous			
Age (years)			
Units: years			
arithmetic mean	57.2	58.8	69.9
standard deviation	± 13.5	± 13.4	± 7.7
Gender categorical			
Gender			
Units: Subjects			
Female	3	3	2
Male	7	7	8
Height			
Height (cm)			
Units: cm			
arithmetic mean	170.6	174.9	175.6
standard deviation	± 11.8	± 12.6	± 9.0
Weight			
Weight (kg)			
Units: kilogram(s)			
arithmetic mean	92.4	82.5	83.2
standard deviation	± 15.1	± 16.8	± 14.0
Systolic Blood Pressure			
Systolic Blood Pressure (mm Hg)			
Units: mm Hg			
arithmetic mean	133.3	130.6	146.1
standard deviation	± 17.3	± 13.9	± 17.8
Diastolic Blood Pressure			
Diastolic Blood Pressure (mm Hg)			
Units: mm Hg			
arithmetic mean	80.0	77.5	81.8

standard deviation	± 7.9	± 5.6	± 11.4
Pulse Rate			
Pulse Rate			
Units: bpm			
arithmetic mean	75.0	77.7	68.5
standard deviation	± 6.3	± 15.8	± 14.3

Reporting group values	Total		
Number of subjects	30		
Age categorical			
Units: Subjects			
Adults (18-64 years)	16		
From 65-84 years	14		
Age continuous			
Age (years)			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Gender			
Units: Subjects			
Female	8		
Male	22		
Height			
Height (cm)			
Units: cm			
arithmetic mean			
standard deviation	-		
Weight			
Weight (kg)			
Units: kilogram(s)			
arithmetic mean			
standard deviation	-		
Systolic Blood Pressure			
Systolic Blood Pressure (mm Hg)			
Units: mm Hg			
arithmetic mean			
standard deviation	-		
Diastolic Blood Pressure			
Diastolic Blood Pressure (mm Hg)			
Units: mm Hg			
arithmetic mean			
standard deviation	-		
Pulse Rate			
Pulse Rate			
Units: bpm			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	Cholecalciferol 300,000 IU
Reporting group description: Single dose of 300, 000 IU cholecalciferol	
Reporting group title	Placebo
Reporting group description: Single dose of Placebo liquid oil	
Reporting group title	Cholecalciferol 600,000 IU
Reporting group description: Single dose of 600, 000 IU cholecalciferol	

Primary: 25(OH)D concentration in serum Baseline

End point title	25(OH)D concentration in serum Baseline[1]
End point description: 25(OH)D concentration in serum	
End point type	Primary
End point timeframe: 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: ng/mL				
arithmetic mean (standard deviation)	19.52 (± 19.39)	19.38 (± 9.25)	15.84 (± 8.01)	

Statistical analyses

No statistical analyses for this end point

Primary: 25(OH)D concentration in serum Week 1

End point title	25(OH)D concentration in serum Week 1[2]
End point description:	
End point type	Primary
End point timeframe: Week 1	

Notes:

[2] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: ng/mL				
arithmetic mean (standard deviation)	31.20 (± 17.54)	18.68 (± 8.88)	40.72 (± 15.41)	

Statistical analyses

No statistical analyses for this end point

Primary: 25(OH)D concentration in serum Week 2

End point title	25(OH)D concentration in serum Week 2[3]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[3] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	8	10	
Units: ng/mL				
arithmetic mean (standard deviation)	32.80 (± 16.87)	18.65 (± 4.67)	39.96 (± 13.11)	

Statistical analyses

No statistical analyses for this end point

Primary: 25(OH)D concentration in serum Week 3

End point title	25(OH)D concentration in serum Week 3[4]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[4] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: ng/mL				
arithmetic mean (standard deviation)	36.09 (± 18.10)	17.96 (± 8.57)	38.48 (± 12.97)	

Statistical analyses

No statistical analyses for this end point

Primary: 25(OH)D concentration in serum Week 4

End point title	25(OH)D concentration in serum Week 4[5]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[5] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	10	10	
Units: ng/mL				
arithmetic mean (standard deviation)	38.55 (± 17.44)	18.28 (± 8.47)	37.76 (± 11.68)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haemoglobin Baseline

End point title	Haematology_Haemoglobin Baseline[6]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[6] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: g/L				
arithmetic mean (standard deviation)	146.20 (± 14.67)	144.60 (± 13.98)	147.20 (± 6.80)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haemoglobin Week 1

End point title	Haematology_Haemoglobin Week 1[7]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[7] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: g/L				
arithmetic mean (standard deviation)	147.90 (± 16.59)	144.56 (± 14.82)	145.50 (± 9.43)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haemoglobin Week 2

End point title	Haematology_Haemoglobin Week 2[8]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[8] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: g/L				
arithmetic mean (standard deviation)	148.20 (± 15.89)	145.70 (± 16.95)	146.60 (± 6.59)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haemoglobin Week 3

End point title	Haematology_Haemoglobin Week 3[9]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[9] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: g/L				
arithmetic mean (standard deviation)	145.33 (± 14.14)	145.80 (± 16.56)	145.20 (± 9.59)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haemoglobin Week 4

End point title	Haematology_Haemoglobin Week 4[10]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[10] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: g/L				
arithmetic mean (standard deviation)	147.80 (± 13.85)	145.10 (± 14.63)	145.00 (± 7.04)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haematocrit Baseline

End point title	Haematology_Haematocrit Baseline[11]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[11] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: L/L				
arithmetic mean (standard deviation)	0.42 (± 0.03)	0.43 (± 0.04)	0.43 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haematocrit Week 1

End point title	Haematology_Haematocrit Week 1[12]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[12] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: L/L				
arithmetic mean (standard deviation)	0.43 (± 0.03)	0.43 (± 0.04)	0.42 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haematocrit Week 2

End point title	Haematology_Haematocrit Week 2[13]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[13] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: L/L				
arithmetic mean (standard deviation)	0.43 (± 0.03)	0.43 (± 0.05)	0.43 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haematocrit Week 3

End point title	Haematology_Haematocrit Week 3[14]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[14] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: L/L				
arithmetic mean (standard deviation)	0.42 (± 0.03)	0.43 (± 0.05)	0.42 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Haematocrit Week 4

End point title	Haematology_Haematocrit Week 4[15]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[15] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: L/L				
arithmetic mean (standard deviation)	0.43 (± 0.03)	0.42 (± 0.04)	0.42 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Platelets Baseline

End point title	Haematology_Platelets Baseline[16]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[16] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	211.60 (± 54.28)	229.00 (± 51.08)	182.40 (± 42.41)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Platelets Week 1

End point title	Haematology_Platelets Week 1[17]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[17] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	207.30 (± 51.93)	220.78 (± 56.40)	185.50 (± 43.77)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Platelets Week 2

End point title	Haematology_Platelets Week 2[18]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[18] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: X10^9/L				
arithmetic mean (standard deviation)	213.20 (± 51.69)	221.90 (± 42.89)	187.10 (± 36.29)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Platelets Week 3

End point title	Haematology_Platelets Week 3[19]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[19] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	215.56 (± 51.02)	220.60 (± 36.79)	188.00 (± 36.93)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Platelets Week 4

End point title	Haematology_Platelets Week 4[20]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[20] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	214.30 (± 50.84)	215.30 (± 45.93)	188.00 (± 42.56)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_White Blood Cell Count Baseline

End point title	Haematology_White Blood Cell Count Baseline[21]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[21] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	6.21 (± 1.36)	6.40 (± 2.04)	6.07 (± 1.97)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_White Blood Cell Count Week 1

End point title	Haematology_White Blood Cell Count Week 1[22]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[22] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	6.06 (± 1.33)	5.66 (± 1.45)	5.74 (± 1.96)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_White Blood Cell Count Week 2

End point title	Haematology_White Blood Cell Count Week 2[23]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[23] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	6.17 (± 1.53)	5.89 (± 1.46)	6.24 (± 1.33)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_White Blood Cell Count Week 3

End point title	Haematology_White Blood Cell Count Week 3[24]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[24] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	5.87 (± 1.58)	5.73 (± 0.97)	5.91 (± 1.56)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_White Blood Cell Count Week 4

End point title	Haematology_White Blood Cell Count Week 4[25]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[25] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	5.90 (± 1.50)	5.90 (± 1.15)	6.02 (± 1.40)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Neutrophils Baseline

End point title	Haematology_Neutrophils Baseline[26]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[26] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	3.96 (± 1.21)	4.07 (± 1.53)	3.58 (± 1.50)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Neutrophils Week 1

End point title	Haematology_Neutrophils Week 1[27]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[27] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	3.70 (± 1.23)	3.23 (± 0.85)	3.26 (± 1.24)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Neutrophils Week 2

End point title	Haematology_Neutrophils Week 2[28]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[28] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	3.71 (± 1.32)	3.45 (± 0.86)	3.53 (± 0.98)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Neutrophils Week 3

End point title	Haematology_Neutrophils Week 3[29]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[29] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	3.59 (± 1.25)	3.32 (± 0.62)	3.37 (± 1.01)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Neutrophils Week 4

End point title	Haematology_Neutrophils Week 4[30]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[30] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	3.64 (± 1.20)	3.60 (± 0.91)	3.44 (± 0.81)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Lymphocytes Baseline

End point title	Haematology_Lymphocytes Baseline[31]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[31] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	1.54 (± 0.48)	1.62 (± 0.55)	1.71 (± 0.47)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Lymphocytes Week 1

End point title	Haematology_Lymphocytes Week 1[32]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[32] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	1.63 (± 0.52)	1.74 (± 0.77)	1.77 (± 0.60)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Lymphocytes Week 2

End point title	Haematology_Lymphocytes Week 2[33]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[33] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	1.69 (± 0.41)	1.70 (± 0.53)	1.93 (± 0.56)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Lymphocytes Week 3

End point title	Haematology_Lymphocytes Week 3[34]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[34] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	1.57 (± 0.54)	1.70 (± 0.45)	1.77 (± 0.54)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Lymphocytes Week 4

End point title	Haematology_Lymphocytes Week 4[35]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[35] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	1.59 (± 0.56)	1.59 (± 0.49)	1.78 (± 0.53)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Monocytes Baseline

End point title	Haematology_Monocytes Baseline[36]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[36] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.53 (± 0.17)	0.53 (± 0.15)	0.56 (± 0.16)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Monocytes Week 1

End point title	Haematology_Monocytes Week 1[37]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[37] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.52 (± 0.14)	0.48 (± 0.16)	0.51 (± 0.19)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Monocytes Week 2

End point title	Haematology_Monocytes Week 2[38]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[38] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.54 (± 0.14)	0.48 (± 0.14)	0.53 (± 0.16)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Monocytes Week 3

End point title	Haematology_Monocytes Week 3[39]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[39] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.48 (± 0.19)	0.49 (± 0.07)	0.53 (± 0.21)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Monocytes Week 4

End point title	Haematology_Monocytes Week 4[40]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[40] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.49 (± 0.15)	0.49 (± 0.17)	0.57 (± 0.19)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Eosinophils Baseline

End point title	Haematology_Eosinophils Baseline[41]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[41] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.15 (± 0.14)	0.18 (± 0.09)	0.17 (± 0.09)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Eosinophils Week 1

End point title	Haematology_Eosinophils Week 1[42]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[42] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.20 (± 0.13)	0.18 (± 0.12)	0.18 (± 0.09)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Eosinophils Week 2

End point title	Haematology_Eosinophils Week 2[43]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[43] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.20 (± 0.12)	0.20 (± 0.12)	0.21 (± 0.10)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Eosinophils Week 3

End point title	Haematology_Eosinophils Week 3[44]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[44] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.18 (± 0.15)	0.20 (± 0.11)	0.22 (± 0.12)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Eosinophils Week 4

End point title	Haematology_Eosinophils Week 4[45]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[45] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.17 (± 0.16)	0.18 (± 0.09)	0.21 (± 0.11)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Basophils Baseline

End point title	Haematology_Basophils Baseline[46]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[46] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.00 (± 0.00)	0.02 (± 0.04)	0.03 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Basophils Week 1

End point title	Haematology_Basophils Week 1[47]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[47] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.01 (± 0.03)	0.01 (± 0.03)	0.03 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Basophils Week 2

End point title	Haematology_Basophils Week 2[48]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[48] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.01 (± 0.03)	0.01 (± 0.03)	0.04 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Basophils Week 3

End point title	Haematology_Basophils Week 3[49]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[49] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.02 (± 0.04)	0.01 (± 0.03)	0.03 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Haematology_Basophils Week 4

End point title	Haematology_Basophils Week 4[50]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[50] - 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: As per Statistical Analysis Plan, haematology data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: 10^9/L				
arithmetic mean (standard deviation)	0.03 (± 0.05)	0.01 (± 0.03)	0.03 (± 0.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Serum Calcium Baseline

End point title	Biochemistry_Serum Calcium Baseline[51]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[51] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.36 (± 0.06)	2.41 (± 0.11)	2.37 (± 0.07)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Serum Calcium Week 1

End point title	Biochemistry_Serum Calcium Week 1[52]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[52] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.36 (± 0.06)	2.39 (± 0.11)	2.36 (± 0.06)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Serum Calcium Week 2

End point title	Biochemistry_Serum Calcium Week 2[53]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[53] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.38 (± 0.06)	2.42 (± 0.11)	2.38 (± 0.07)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Serum Calcium Week 3

End point title	Biochemistry_Serum Calcium Week 3[54]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[54] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.38 (± 0.07)	2.38 (± 0.07)	2.36 (± 0.06)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Serum Calcium Week 4

End point title	Biochemistry_Serum Calcium Week 4[55]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[55] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.35 (± 0.09)	2.39 (± 0.08)	2.37 (± 0.07)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Corrected Serum Calcium Baseline

End point title	Biochemistry_Corrected Serum Calcium Baseline[56]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[56] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.35 (± 0.06)	2.38 (± 0.08)	2.36 (± 0.08)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Corrected Serum Calcium Week 1

End point title	Biochemistry_Corrected Serum Calcium Week 1[57]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[57] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.37 (± 0.05)	2.37 (± 0.08)	2.38 (± 0.07)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Corrected Serum Calcium Week 2

End point title	Biochemistry_Corrected Serum Calcium Week 2[58]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[58] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.37 (± 0.05)	2.39 (± 0.08)	2.40 (± 0.07)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Corrected Serum Calcium Week 3

End point title	Biochemistry_Corrected Serum Calcium Week 3[59]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[59] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.37 (± 0.07)	2.36 (± 0.06)	2.38 (± 0.07)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Corrected Serum Calcium Week 4

End point title	Biochemistry_Corrected Serum Calcium Week 4[60]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[60] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	2.33 (± 0.06)	2.37 (± 0.07)	2.38 (± 0.06)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Albumin Baseline

End point title	Biochemistry_Albumin Baseline[61]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[61] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: g/L				
arithmetic mean (standard deviation)	44.60 (± 3.69)	45.80 (± 2.70)	44.70 (± 2.50)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Albumin Week 1

End point title	Biochemistry_Albumin Week 1[62]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[62] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: g/L				
arithmetic mean (standard deviation)	43.50 (± 3.98)	45.40 (± 2.59)	42.90 (± 1.73)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Albumin Week 2

End point title	Biochemistry_Albumin Week 2[63]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[63] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: g/L				
arithmetic mean (standard deviation)	44.40 (± 2.99)	45.60 (± 3.03)	43.10 (± 1.85)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Albumin Week 3

End point title	Biochemistry_Albumin Week 3[64]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[64] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: g/L				
arithmetic mean (standard deviation)	44.67 (± 3.64)	45.50 (± 2.46)	43.00 (± 1.76)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Albumin Week 4

End point title	Biochemistry_Albumin Week 4[65]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[65] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: g/L				
arithmetic mean (standard deviation)	44.80 (± 2.86)	45.60 (± 2.32)	43.10 (± 1.97)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Sodium Baseline

End point title	Biochemistry_Sodium Baseline[66]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[66] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	140.90 (± 2.56)	141.10 (± 2.02)	140.40 (± 2.59)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Sodium Week 1

End point title	Biochemistry_Sodium Week 1[67]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[67] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	141.80 (± 2.82)	141.40 (± 1.71)	141.20 (± 2.20)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Sodium Week 2

End point title	Biochemistry_Sodium Week 2[68]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[68] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	139.70 (± 2.79)	141.40 (± 1.84)	141.00 (± 1.49)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Sodium Week 3

End point title	Biochemistry_Sodium Week 3[69]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[69] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	140.89 (± 2.57)	140.10 (± 2.08)	141.00 (± 1.76)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Sodium Week 4

End point title	Biochemistry_Sodium Week 4[70]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[70] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	140.50 (± 2.17)	140.70 (± 2.36)	141.20 (± 2.20)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Potassium Baseline

End point title	Biochemistry_Potassium Baseline[71]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[71] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	4.22 (± 0.22)	4.25 (± 0.38)	4.54 (± 0.34)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Potassium Week 1

End point title	Biochemistry_Potassium Week 1[72]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[72] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	4.16 (± 0.29)	4.09 (± 0.16)	4.18 (± 0.21)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Potassium Week 2

End point title	Biochemistry_Potassium Week 2[73]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[73] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	4.12 (± 0.25)	4.17 (± 0.39)	4.23 (± 0.25)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Potassium Week 3

End point title	Biochemistry_Potassium Week 3[74]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[74] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	4.07 (± 0.34)	4.10 (± 0.13)	4.28 (± 0.30)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Potassium Week 4

End point title	Biochemistry_Potassium Week 4[75]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[75] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	4.08 (± 0.34)	4.07 (± 0.25)	4.22 (± 0.23)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Chloride Baseline

End point title	Biochemistry_Chloride Baseline[76]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[76] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	104.10 (± 1.79)	105.30 (± 1.57)	102.40 (± 2.07)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Chloride Week 1

End point title	Biochemistry_Chloride Week 1[77]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[77] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	106.10 (± 2.77)	105.90 (± 1.66)	102.40 (± 1.90)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Chloride Week 2

End point title	Biochemistry_Chloride Week 2[78]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[78] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	104.00 (± 2.54)	106.40 (± 1.17)	101.80 (± 1.23)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Chloride Week 3

End point title	Biochemistry_Chloride Week 3[79]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[79] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	104.67 (± 2.35)	106.00 (± 1.94)	102.30 (± 1.89)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Chloride Week 4

End point title	Biochemistry_Chloride Week 4[80]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[80] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	104.40 (± 2.50)	106.10 (± 2.56)	102.70 (± 2.00)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Creatinine Baseline

End point title	Biochemistry_Creatinine Baseline[81]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[81] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	74.00 (± 12.29)	78.50 (± 16.57)	84.30 (± 15.56)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Creatinine Week 1

End point title	Biochemistry_Creatinine Week 1[82]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[82] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	73.60 (± 12.70)	77.60 (± 14.75)	87.00 (± 17.16)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Creatinine Week 2

End point title	Biochemistry_Creatinine Week 2[83]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[83] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	76.60 (± 13.67)	77.80 (± 14.45)	89.60 (± 17.51)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Creatinine Week 3

End point title	Biochemistry_Creatinine Week 3[84]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[84] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	79.56 (± 12.26)	80.50 (± 15.86)	86.60 (± 17.48)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Creatinine Week 4

End point title	Biochemistry_Creatinine Week 4[85]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[85] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	73.40 (± 12.16)	78.60 (± 15.32)	86.30 (± 15.08)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Glucose, Serum Baseline

End point title	Biochemistry_Glucose, Serum Baseline[86]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[86] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	6.99 (± 4.89)	5.55 (± 0.61)	5.99 (± 1.61)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Glucose, Serum Week 1

End point title	Biochemistry_Glucose, Serum Week 1[87]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[87] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	6.93 (± 5.47)	5.58 (± 0.92)	6.44 (± 2.14)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Glucose, Serum Week 2

End point title	Biochemistry_Glucose, Serum Week 2[88]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[88] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	7.40 (± 5.43)	5.69 (± 0.54)	6.87 (± 1.80)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Glucose, Serum Week 3

End point title	Biochemistry_Glucose, Serum Week 3[89]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[89] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	8.57 (± 6.48)	5.23 (± 0.45)	6.68 (± 2.00)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Glucose, Serum Week 4

End point title	Biochemistry_Glucose, Serum Week 4[90]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[90] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	7.56 (± 5.53)	5.35 (± 0.36)	6.49 (± 2.01)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Alkaline Phosphatase Baseline

End point title	Biochemistry_Alkaline Phosphatase Baseline[91]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[91] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	91.30 (± 31.14)	87.70 (± 22.75)	112.20 (± 71.41)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Alkaline Phosphatase Week 1

End point title	Biochemistry_Alkaline Phosphatase Week 1[92]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[92] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	86.90 (± 23.46)	88.20 (± 20.14)	107.10 (± 76.27)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Alkaline Phosphatase Week 2

End point title	Biochemistry_Alkaline Phosphatase Week 2[93]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[93] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	86.70 (± 24.82)	86.60 (± 20.02)	118.10 (± 106.36)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Alkaline Phosphatase Week 3

End point title	Biochemistry_Alkaline Phosphatase Week 3[94]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[94] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: U/L				
arithmetic mean (standard deviation)	86.56 (± 22.25)	83.40 (± 18.79)	119.60 (± 119.65)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Alkaline Phosphatase Week 4

End point title	Biochemistry_Alkaline Phosphatase Week 4[95]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[95] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	84.70 (± 21.80)	84.70 (± 19.40)	138.30 (± 171.89)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Blood Urea Baseline

End point title	Biochemistry_Blood Urea Baseline[96]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[96] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	5.58 (± 1.37)	4.28 (± 1.38)	5.70 (± 1.33)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Blood Urea Week 1

End point title	Biochemistry_Blood Urea Week 1[97]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[97] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	5.81 (± 1.60)	4.63 (± 1.59)	5.94 (± 1.31)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Blood Urea Week 2

End point title	Biochemistry_Blood Urea Week 2[98]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[98] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	5.25 (± 1.52)	4.61 (± 1.31)	6.16 (± 1.34)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Blood Urea Week 3

End point title	Biochemistry_Blood Urea Week 3[99]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[99] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	5.74 (± 1.68)	4.76 (± 1.27)	5.64 (± 1.16)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Blood Urea Week 4

End point title	Biochemistry_Blood Urea Week 4[100]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[100] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	5.30 (± 1.08)	4.69 (± 1.41)	6.16 (± 1.90)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGOT/AST Baseline

End point title	Biochemistry_SGOT/AST Baseline[101]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[101] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: U/L				
arithmetic mean (standard deviation)	20.11 (± 5.01)	24.40 (± 5.82)	38.80 (± 48.78)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGOT/AST Week 1

End point title	Biochemistry_SGOT/AST Week 1[102]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[102] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: U/L				
arithmetic mean (standard deviation)	20.44 (± 5.27)	28.10 (± 13.26)	30.90 (± 24.42)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGOT/AST Week 2

End point title	Biochemistry_SGOT/AST Week 2[103]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[103] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	21.80 (± 6.36)	28.50 (± 12.62)	35.30 (± 39.07)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGOT/AST Week 3

End point title	Biochemistry_SGOT/AST Week 3[104]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[104] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: U/L				
arithmetic mean (standard deviation)	20.44 (± 5.48)	26.20 (± 9.40)	27.80 (± 17.61)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGOT/AST Week 4

End point title	Biochemistry_SGOT/AST Week 4[105]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[105] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	22.10 (± 7.06)	27.10 (± 10.45)	38.20 (± 49.61)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGPT/ALT Baseline

End point title	Biochemistry_SGPT/ALT Baseline[106]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[106] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	27.10 (± 12.81)	20.60 (± 7.59)	36.50 (± 54.01)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGPT/ALT Week 1

End point title	Biochemistry_SGPT/ALT Week 1[107]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[107] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	25.30 (± 6.75)	22.40 (± 11.73)	30.50 (± 37.02)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGPT/ALT Week 2

End point title	Biochemistry_SGPT/ALT Week 2[108]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[108] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	26.70 (± 8.31)	24.30 (± 16.08)	39.20 (± 63.83)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGPT/ALT Week 3

End point title	Biochemistry_SGPT/ALT Week 3[109]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[109] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: U/L				
arithmetic mean (standard deviation)	25.11 (± 9.94)	21.50 (± 9.58)	29.60 (± 37.77)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_SGPT/ALT Week 4

End point title	Biochemistry_SGPT/ALT Week 4[110]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[110] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: U/L				
arithmetic mean (standard deviation)	27.10 (± 13.64)	23.00 (± 11.06)	37.90 (± 62.84)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Bilirubin, Total Baseline

End point title	Biochemistry_Bilirubin, Total Baseline[111]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[111] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	9.30 (± 5.77)	10.30 (± 6.63)	12.20 (± 4.59)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Bilirubin, Total Week 1

End point title	Biochemistry_Bilirubin, Total Week 1[112]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[112] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	8.90 (± 4.09)	10.60 (± 7.11)	11.30 (± 3.30)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Bilirubin, Total Week 2

End point title	Biochemistry_Bilirubin, Total Week 2[113]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[113] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	10.00 (± 4.69)	10.50 (± 6.75)	13.20 (± 5.14)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Bilirubin, Total Week 3

End point title	Biochemistry_Bilirubin, Total Week 3[114]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[114] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	9.78 (± 5.56)	11.50 (± 7.07)	11.50 (± 4.84)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Bilirubin, Total Week 4

End point title	Biochemistry_Bilirubin, Total Week 4[115]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[115] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: umol/L				
arithmetic mean (standard deviation)	10.00 (± 4.97)	12.10 (± 7.13)	12.00 (± 4.83)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Phosphorus Baseline

End point title	Biochemistry_Phosphorus Baseline[116]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[116] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	1.05 (± 0.18)	0.97 (± 0.18)	0.86 (± 0.17)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Phosphorus Week 1

End point title	Biochemistry_Phosphorus Week 1[117]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[117] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	1.01 (± 0.14)	0.94 (± 0.20)	0.86 (± 0.19)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Phosphorus Week 2

End point title	Biochemistry_Phosphorus Week 2[118]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[118] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	1.02 (± 0.19)	0.93 (± 0.22)	0.86 (± 0.20)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Phosphorus Week 3

End point title	Biochemistry_Phosphorus Week 3[119]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[119] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	1.02 (± 0.13)	0.92 (± 0.19)	0.82 (± 0.18)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_Phosphorus Week 4

End point title	Biochemistry_Phosphorus Week 4[120]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[120] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mmol/L				
arithmetic mean (standard deviation)	1.04 (± 0.18)	0.92 (± 0.20)	0.84 (± 0.18)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_eGFR Baseline

End point title	Biochemistry_eGFR Baseline[121]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[121] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mL/min				
arithmetic mean (standard deviation)	60.00 (± 0.00)	60.00 (± 0.00)	62.50 (± 6.10)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_eGFR Week 1

End point title	Biochemistry_eGFR Week 1[122]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[122] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mL/min				
arithmetic mean (standard deviation)	60.00 (± 0.00)	60.00 (± 0.00)	59.30 (± 1.89)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_eGFR Week 2

End point title	Biochemistry_eGFR Week 2[123]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[123] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mL/min				
arithmetic mean (standard deviation)	60.00 (± 0.00)	60.00 (± 0.00)	58.50 (± 2.55)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_eGFR Week 3

End point title	Biochemistry_eGFR Week 3[124]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[124] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: mL/min				
arithmetic mean (standard deviation)	60.00 (± 0.00)	59.80 (± 0.63)	59.20 (± 2.20)	

Statistical analyses

No statistical analyses for this end point

Primary: Biochemistry_eGFR Week 4

End point title	Biochemistry_eGFR Week 4[125]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[125] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: mL/min				
arithmetic mean (standard deviation)	60.00 (± 0.00)	60.00 (± 0.00)	59.40 (± 1.58)	

Statistical analyses

No statistical analyses for this end point

Primary: Serum 25(OH)D >/= 33 ng/mL Baseline

End point title	Serum 25(OH)D >/= 33 ng/mL Baseline[126]

End point description:

Number of patients with a serum 25(OH)D concentration of greater than or equal to 33 ng/mL

End point type	Primary

End point timeframe:

Baseline

Notes:

[126] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	10	
Units: Patients	1	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Serum 25(OH)D >/= 33 ng/mL Week 1

End point title	Serum 25(OH)D >/= 33 ng/mL Week 1[127]

End point description:

Number of patients with serum 25(OH)D concentrations greater than or equal to 33 ng/mL

End point type	Primary

End point timeframe:

Week 1

Notes:

[127] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	5	1	7	

Statistical analyses

No statistical analyses for this end point

Primary: Serum 25(OH)D >/= 33 ng/mL Week 2

End point title	Serum 25(OH)D >/= 33 ng/mL Week 2[128]

End point description:

Number of patients with serum 25(OH)D concentration greater than or equal to 33 ng/mL

End point type	Primary

End point timeframe:

Week 2

Notes:

[128] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	8	10	
Units: Patients	5	0	7	

Statistical analyses

No statistical analyses for this end point

Primary: Serum 25(OH)D >/= 33 ng/mL Week 3

End point title	Serum 25(OH)D >/= 33 ng/mL Week 3[129]

End point description:

Number of patients with serum 25(OH)D concentration greater than or equal to 33 ng/mL

End point type	Primary

End point timeframe:

Week 3

Notes:

[129] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	5	1	7	

Statistical analyses

No statistical analyses for this end point

Primary: Serum 25(OH)D >/= 33 ng/mL Week 4

End point title	Serum 25(OH)D >/= 33 ng/mL Week 4[130]

End point description:

Number of patients with serum 25(OH)D concentration greater than or equal to 33 ng/mL

End point type	Primary

End point timeframe:

Week 4

Notes:

[130] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	10	10	
Units: Patients	5	0	7	

Statistical analyses

No statistical analyses for this end point

Primary: Serum corrected Calcium >/= 2.65mmol/I Baseline

End point title	Serum corrected Calcium >/= 2.65mmol/I Baseline[131]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[131] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Has fallen in the last week Baseline

End point title	Falls_Has fallen in the last week Baseline[132]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[132] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Has fallen in the last week Week 2

End point title	Falls_Has fallen in the last week Week 2[133]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[133] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Has fallen in the last week Week 3

End point title	Falls_Has fallen in the last week Week 3[134]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[134] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Has fallen in the last week Week 4

End point title	Falls_Has fallen in the last week Week 4[135]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[135] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Serum corrected Calcium >/= 2.65mmol/I Week 1

End point title	Serum corrected Calcium >/= 2.65mmol/I Week 1[136]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[136] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Serum corrected Calcium >/= 2.65mmol/I Week 2

End point title	Serum corrected Calcium >/= 2.65mmol/I Week 2[137]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[137] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Serum corrected Calcium >/= 2.65mmol/I Week 3

End point title	Serum corrected Calcium >/= 2.65mmol/I Week 3[138]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[138] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patient	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Serum corrected Calcium >/= 2.65mmol/I Week 4

End point title	Serum corrected Calcium >/= 2.65mmol/I Week 4[139]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[139] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Times fallen in the last week Baseline

End point title	Falls_Times fallen in the last week Baseline[140][141]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[140] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[141] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	1			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Times fallen in the last week Week 2

End point title	Falls_Times fallen in the last week Week 2[142][143]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[142] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[143] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	1			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Times fallen in the last week Week 4

End point title	Falls_Times fallen in the last week Week 4[144][145]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[144] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[145] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	1			

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Other Vitamins Baseline

End point title	Diet_Other Vitamins Baseline[146]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[146] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Other Vitamins Week 1

End point title	Diet_Other Vitamins Week 1[147]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[147] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Other Vitamins Week 2

End point title	Diet_Other Vitamins Week 2[148]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[148] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Other Vitamins Week 3

End point title	Diet_Other Vitamins Week 3[149]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[149] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Other Vitamins Week 4

End point title	Diet_Other Vitamins Week 4[150]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[150] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Fish Oil Baseline

End point title	Diet_Fish Oil Baseline[151]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[151] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Fish Oil Week 1

End point title	Diet_Fish Oil Week 1[152]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[152] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Fish Oil Week 2

End point title	Diet_Fish Oil Week 2[153]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[153] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Fish Oil Week 3

End point title	Diet_Fish Oil Week 3[154]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[154] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Fish Oil Week 4

End point title	Diet_Fish Oil Week 4[155]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[155] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Baseline

End point title	Falls_Location Baseline[156][157]

End point description:

Inside the house

End point type	Primary

End point timeframe:

Baseline

Notes:

[156] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[157] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	1			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Baseline

End point title	Falls_Location Baseline[158][159]

End point description:

Inside house_walking up/down stairs

End point type	Primary

End point timeframe:

Baseline

Notes:

[158] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[159] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	1			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Baseline

End point title	Falls_Location Baseline[160][161]

End point description:

Home entrance/in garden

End point type	Primary

End point timeframe:

Baseline

Notes:

[160] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[161] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Baseline

End point title	Falls_Location Baseline[162][163]

End point description:

Away from home

End point type	Primary

End point timeframe:

Baseline

Notes:

[162] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[163] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Week 2

End point title	Falls_Location Week 2[164][165]

End point description:

Inside the house

End point type	Primary

End point timeframe:

Week 2

Notes:

[164] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[165] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Week 2

End point title	Falls_Location Week 2[166][167]

End point description:

Home entrance/in garden

End point type	Primary

End point timeframe:

Week 2

Notes:

[166] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[167] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	1			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Week 2

End point title	Falls_Location Week 2[168][169]

End point description:

Home entrance/in garden_In the garden

End point type	Primary

End point timeframe:

Week 2

Notes:

[168] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[169] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all

the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	1			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Week 2

End point title	Falls_Location Week 2[170][171]
End point description:	
Away from home	
End point type	Primary
End point timeframe:	
Week 2	

Notes:

[170] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[171] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Week 4

End point title	Falls_Location Week 4[172][173]
End point description:	
Inside the house	
End point type	Primary
End point timeframe:	
Week 4	

Notes:

[172] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[173] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Week 4

End point title	Falls_Location Week 4[174][175]

End point description:

Home entrance/in garden

End point type	Primary

End point timeframe:

Week 4

Notes:

[174] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[175] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Week 4

End point title	Falls_Location Week 4[176][177]

End point description:

Away from home

End point type	Primary

End point timeframe:

Week 4

Notes:

[176] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[177] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Location Week 4

End point title	Falls_Location Week 4[178][179]

End point description:

Away from home_On a kerb/gutter

End point type	Primary

End point timeframe:

Week 4

Notes:

[178] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[179] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Times Fallen	1			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Injured as a result Baseline

End point title	Falls_Injured as a result Baseline[180][181]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[180] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[181] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Patients	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Injured as a result Week 2

End point title	Falls_Injured as a result Week 2[182][183]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[182] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[183] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Patients	0			

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Injured as a result Week 4

End point title	Falls_Injured as a result Week 4[184][185]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[184] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.
[185] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Patients	0			

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Baseline

End point title	Diet_Times per week eat oily fish Baseline[186]

End point description:

None

End point type	Primary

End point timeframe:

Baseline

Notes:

[186] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	4	7	5	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Baseline

End point title	Diet_Times per week eat oily fish Baseline[187]

End point description:

Once

End point type	Primary

End point timeframe:

Baseline

Notes:

[187] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	1	2	2	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Baseline

End point title	Diet_Times per week eat oily fish Baseline[188]

End point description:

Twice

End point type	Primary

End point timeframe:

Baseline

Notes:

[188] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	1	1	3	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Baseline

End point title	Diet_Times per week eat oily fish Baseline[189]

End point description:

Three or More

End point type	Primary

End point timeframe:

Baseline

Notes:

[189] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 1

End point title	Diet_Times per week eat oily fish Week 1[190]

End point description:

None

End point type	Primary

End point timeframe:

Week 1

Notes:

[190] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	10	10	10	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 1

End point title	Diet_Times per week eat oily fish Week 1[191]

End point description:

Once

End point type	Primary

End point timeframe:

Week 1

Notes:

[191] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 1

End point title	Diet_Times per week eat oily fish Week 1[192]

End point description:

Twice

End point type	Primary

End point timeframe:

Week 1

Notes:

[192] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Timee Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 1

End point title	Diet_Times per week eat oily fish Week 1[193]

End point description:

Three or more

End point type	Primary

End point timeframe:

Week 1

Notes:

[193] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 2

End point title	Diet_Times per week eat oily fish Week 2[194]

End point description:

None

End point type	Primary

End point timeframe:

Week 2

Notes:

[194] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	10	10	10	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 2

End point title	Diet_Times per week eat oily fish Week 2[195]

End point description:

Once

End point type	Primary

End point timeframe:

Week 2

Notes:

[195] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 2

End point title	Diet_Times per week eat oily fish Week 2[196]

End point description:

Twice

End point type	Primary

End point timeframe:

Week 2

Notes:

[196] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 2

End point title	Diet_Times per week eat oily fish Week 2[197]

End point description:

Three or more

End point type	Primary

End point timeframe:

Week 2

Notes:

[197] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 3

End point title	Diet_Times per week eat oily fish Week 3[198]

End point description:

None

End point type	Primary

End point timeframe:

Week 3

Notes:

[198] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Times Per Week	9	10	9	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 3

End point title	Diet_Times per week eat oily fish Week 3[199]

End point description:

Once

End point type	Primary

End point timeframe:

Week 3

Notes:

[199] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Times Per Week	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 3

End point title	Diet_Times per week eat oily fish Week 3[200]

End point description:

Twice

End point type	Primary

End point timeframe:

Week 3

Notes:

[200] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 3

End point title	Diet_Times per week eat oily fish Week 3[201]

End point description:

Three or more

End point type	Primary

End point timeframe:

Week 3

Notes:

[201] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 4

End point title	Diet_Times per week eat oily fish Week 4[202]

End point description:

None

End point type	Primary

End point timeframe:

Week 4

Notes:

[202] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	9	
Units: Times Per Week	9	10	8	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 4

End point title	Diet_Times per week eat oily fish Week 4[203]

End point description:

Once

End point type	Primary

End point timeframe:

Week 4

Notes:

[203] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	9	
Units: Times Per Week	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 4

End point title	Diet_Times per week eat oily fish Week 4[204]

End point description:

Twice

End point type	Primary

End point timeframe:

Week 4

Notes:

[204] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	9	
Units: Diet_Times per week eat oily fish	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat oily fish Week 4

End point title	Diet_Times per week eat oily fish Week 4[205]

End point description:

Three or more

End point type	Primary

End point timeframe:

Week 4

Notes:

[205] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	9	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Baseline

End point title	Diet_Times per week eat mushrooms Baseline[206]

End point description:

None

End point type	Primary

End point timeframe:

Baseline

Notes:

[206] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times per week	4	2	4	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Baseline

End point title	Diet_Times per week eat mushrooms Baseline[207]

End point description:

Once

End point type	Primary

End point timeframe:

Baseline

Notes:

[207] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	2	4	4	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Baseline

End point title	Diet_Times per week eat mushrooms Baseline[208]

End point description:

Twice

End point type	Primary

End point timeframe:

Baseline

Notes:

[208] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	3	2	2	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Baseline

End point title	Diet_Times per week eat mushrooms Baseline[209]

End point description:

Three or more

End point type	Primary

End point timeframe:

Baseline

Notes:

[209] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	1	2	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 1

End point title	Diet_Times per week eat mushrooms Week 1[210]

End point description:

None

End point type	Primary

End point timeframe:

Week 1

Notes:

[210] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	10	9	8	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 1

End point title	Diet_Times per week eat mushrooms Week 1[211]

End point description:

Once

End point type	Primary

End point timeframe:

Week 1

Notes:

[211] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	2	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 1

End point title	Diet_Times per week eat mushrooms Week 1[212]

End point description:

Twice

End point type	Primary

End point timeframe:

Week 1

Notes:

[212] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 1

End point title	Diet_Times per week eat mushrooms Week 1[213]

End point description:

Three of more

End point type	Primary

End point timeframe:

Week 1

Notes:

[213] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 2

End point title	Diet_Times per week eat mushrooms Week 2[214]

End point description:

None

End point type	Primary

End point timeframe:

Week 2

Notes:

[214] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	9	8	10	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 2

End point title	Diet_Times per week eat mushrooms Week 2[215]

End point description:

Once

End point type	Primary

End point timeframe:

Week 2

Notes:

[215] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	1	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 2

End point title	Diet_Times per week eat mushrooms Week 2[216]

End point description:

Twice

End point type	Primary

End point timeframe:

Week 2

Notes:

[216] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 2

End point title	Diet_Times per week eat mushrooms Week 2[217]

End point description:

Three or more

End point type	Primary

End point timeframe:

Week 2

Notes:

[217] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Times Per Week	0	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 3

End point title	Diet_Times per week eat mushrooms Week 3[218]

End point description:

None

End point type	Primary

End point timeframe:

Week 3

Notes:

[218] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Times Per Week	9	9	10	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 3

End point title	Diet_Times per week eat mushrooms Week 3[219]

End point description:

Once

End point type	Primary

End point timeframe:

Week 3

Notes:

[219] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 3

End point title	Diet_Times per week eat mushrooms Week 3[220]

End point description:

Twice

End point type	Primary

End point timeframe:

Week 3

Notes:

[220] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 3

End point title	Diet_Times per week eat mushrooms Week 3[221]

End point description:

Three or more

End point type	Primary

End point timeframe:

Week 3

Notes:

[221] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Times Per Week	0	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 4

End point title	Diet_Times per week eat mushrooms Week 4[222]

End point description:

None

End point type	Primary

End point timeframe:

Week 4

Notes:

[222] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	9	
Units: Times Per Week	10	8	8	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 4

End point title	Diet_Times per week eat mushrooms Week 4[223]

End point description:

Once

End point type	Primary

End point timeframe:

Week 4

Notes:

[223] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	9	
Units: Times Per Week	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 4

End point title	Diet_Times per week eat mushrooms Week 4[224]

End point description:

Twice

End point type	Primary

End point timeframe:

Week 4

Notes:

[224] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	9	
Units: Times Per Week	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Diet_Times per week eat mushrooms Week 4

End point title	Diet_Times per week eat mushrooms Week 4[225]

End point description:

Three or more

End point type	Primary

End point timeframe:

Week 4

Notes:

[225] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	9	9	
Units: Times Per Week	0	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of Appetite Baseline

End point title	Toxicity_Loss of Appetite Baseline[226]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[226] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of Appetite Week 1

End point title	Toxicity_Loss of Appetite Week 1[227]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[227] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of Appetite Week 2

End point title	Toxicity_Loss of Appetite Week 2[228]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[228] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of Appetite Week 3

End point title	Toxicity_Loss of Appetite Week 3[229]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[229] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	2	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of Appetite Week 4

End point title	Toxicity_Loss of Appetite Week 4[230]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[230] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Nausea Baseline

End point title	Toxicity_Nausea Baseline[231]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[231] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Nausea Week 1

End point title	Toxicity_Nausea Week 1[232]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[232] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	3	2	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Nausea Week 2

End point title	Toxicity_Nausea Week 2[233]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[233] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	9	
Units: Patients	1	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Nausea Week 3

End point title	Toxicity_Nausea Week 3[234]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[234] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Nausea Week 4

End point title	Toxicity_Nausea Week 4[235]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[235] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Vomiting Baseline

End point title	Toxicity_Vomiting Baseline[236]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[236] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Vomiting Week 1

End point title	Toxicity_Vomiting Week 1[237]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[237] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Vomiting Week 2

End point title	Toxicity_Vomiting Week 2[238]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[238] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Vomiting Week 3

End point title	Toxicity_Vomiting Week 3[239]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[239] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Vomiting Week 4

End point title	Toxicity_Vomiting Week 4[240]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[240] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Diarrhoea Baseline

End point title	Toxicity_Diarrhoea Baseline[241]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[241] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Diarrhoea Week 1

End point title	Toxicity_Diarrhoea Week 1[242]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[242] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	9	
Units: Patients	4	2	3	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Diarrhoea Week 2

End point title	Toxicity_Diarrhoea Week 2[243]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[243] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Diarrhoea Week 3

End point title	Toxicity_Diarrhoea Week 3[244]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[244] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Diarrhoea Week 4

End point title	Toxicity_Diarrhoea Week 4[245]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[245] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of weight Baseline

End point title	Toxicity_Loss of weight Baseline[246]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[246] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of weight Week 1

End point title	Toxicity_Loss of weight Week 1[247]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[247] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of weight Week 2

End point title	Toxicity_Loss of weight Week 2[248]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[248] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of weight Week 3

End point title	Toxicity_Loss of weight Week 3[249]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[249] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Loss of weight Week 4

End point title	Toxicity_Loss of weight Week 4[250]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[250] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Headache Baseline

End point title	Toxicity_Headache Baseline[251]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[251] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	4	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Headache Week 1

End point title	Toxicity_Headache Week 1[252]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[252] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	4	0	2	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Headache Week 2

End point title	Toxicity_Headache Week 2[253]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[253] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Headache Week 3

End point title	Toxicity_Headache Week 3[254]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[254] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Headache Week 4

End point title	Toxicity_Headache Week 4[255]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[255] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Rise at night to pass urine Baseline

End point title	Toxicity_Rise at night to pass urine Baseline[256]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[256] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	4	3	4	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Rise at night to pass urine Week 1

End point title	Toxicity_Rise at night to pass urine Week 1[257]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[257] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	2	3	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Rise at night to pass urine Week 2

End point title	Toxicity_Rise at night to pass urine Week 2[258]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[258] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	2	3	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Rise at night to pass urine Week 3

End point title	Toxicity_Rise at night to pass urine Week 3[259]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[259] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	2	2	3	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Rise at night to pass urine Week 4

End point title	Toxicity_Rise at night to pass urine Week 4[260]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[260] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	9	
Units: Patients	1	1	3	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Thirst Baseline

End point title	Toxicity_Thirst Baseline[261]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[261] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Thirst Week 1

End point title	Toxicity_Thirst Week 1[262]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[262] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Thirst Week 2

End point title	Toxicity_Thirst Week 2[263]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[263] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	3	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Thirst Week 2

End point title	Toxicity_Thirst Week 2[264]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[264] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	3	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Thirst Week 3

End point title	Toxicity_Thirst Week 3[265]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[265] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Thirst Week 4

End point title	Toxicity_Thirst Week 4[266]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[266] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	3	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Dizziness Baseline

End point title	Toxicity_Dizziness Baseline[267]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[267] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Dizziness Week 1

End point title	Toxicity_Dizziness Week 1[268]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[268] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Dizziness Week 2

End point title	Toxicity_Dizziness Week 2[269]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[269] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	2	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Dizziness Week 3

End point title	Toxicity_Dizziness Week 3[270]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[270] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Dizziness Week 4

End point title	Toxicity_Dizziness Week 4[271]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[271] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Constipation Baseline

End point title	Toxicity_Constipation Baseline[272]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[272] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Constipation Week 1

End point title	Toxicity_Constipation Week 1[273]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[273] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	2	2	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Constipation Week 2

End point title	Toxicity_Constipation Week 2[274]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[274] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Constipation Week 3

End point title	Toxicity_Constipation Week 3[275]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[275] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Constipation Week 4

End point title	Toxicity_Constipation Week 4[276]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[276] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	1	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Fatigue Baseline

End point title	Toxicity_Fatigue Baseline[277]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[277] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	4	3	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Fatigue Week 1

End point title	Toxicity_Fatigue Week 1[278]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[278] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	2	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Fatigue Week 2

End point title	Toxicity_Fatigue Week 2[279]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[279] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	3	1	2	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Fatigue Week 3

End point title	Toxicity_Fatigue Week 3[280]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[280] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	4	1	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Fatigue Week 4

End point title	Toxicity_Fatigue Week 4[281]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[281] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	5	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Bone Pain Baseline

End point title	Toxicity_Bone Pain Baseline[282]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[282] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	3	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Bone Pain Week 1

End point title	Toxicity_Bone Pain Week 1[283]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[283] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	9	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Bone Pain Week 2

End point title	Toxicity_Bone Pain Week 2[284]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[284] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Bone Pain Week 3

End point title	Toxicity_Bone Pain Week 3[285]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[285] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Bone Pain Week 4

End point title	Toxicity_Bone Pain Week 4[286]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[286] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Muscle Weakness Baseline

End point title	Toxicity_Muscle Weakness Baseline[287]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[287] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	3	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Muscle Weakness Week 1

End point title	Toxicity_Muscle Weakness Week 1[288]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[288] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Muscle Weakness Week 2

End point title	Toxicity_Muscle Weakness Week 2[289]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[289] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	3	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Muscle Weakness Week 3

End point title	Toxicity_Muscle Weakness Week 3[290]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[290] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Muscle Weakness Week 4

End point title	Toxicity_Muscle Weakness Week 4[291]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[291] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Abdominal Pain Baseline

End point title	Toxicity_Abdominal Pain Baseline[292]

End point description:

End point type	Primary

End point timeframe:

Baseline

Notes:

[292] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Abdominal Pain Week 1

End point title	Toxicity_Abdominal Pain Week 1[293]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[293] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	1	2	2	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Abdominal Pain Week 2

End point title	Toxicity_Abdominal Pain Week 2[294]

End point description:

End point type	Primary

End point timeframe:

Week 2

Notes:

[294] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Abdominal Pain Week 3

End point title	Toxicity_Abdominal Pain Week 3[295]

End point description:

End point type	Primary

End point timeframe:

Week 3

Notes:

[295] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	10	10	
Units: Patients	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Toxicity_Abdominal Pain Week 4

End point title	Toxicity_Abdominal Pain Week 4[296]

End point description:

End point type	Primary

End point timeframe:

Week 4

Notes:

[296] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	2	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Falls_Has fallen in the last week Week 1

End point title	Falls_Has fallen in the last week Week 1[297]

End point description:

End point type	Primary

End point timeframe:

Week 1

Notes:

[297] - 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: As per Statistical Analysis Plan, biochemistry data analysed using descriptive statistics only.

End point values	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: Patients	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Baseline, week 1, 2, 3 and 4	
Adverse event reporting additional description: Patients were asked about adverse events at each study visit.	
Assessment type	Systematic

Dictionary used	
Dictionary name	NCI CTCAE
Dictionary version	4.03

Reporting groups	
Reporting group title	Cholecalciferol 300,000 IU
Reporting group description: Participants receiving cholecalciferol 300,000 IU	
Reporting group title	Placebo
Reporting group description: Participants receiving placebo	
Reporting group title	Cholecalciferol 600,000 IU
Reporting group description: Participants receiving 600,000 IU Cholecalciferol	

Serious adverse events	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Cholecalciferol 300,000 IU	Placebo	Cholecalciferol 600,000 IU
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 10 (60.00%)	2 / 10 (20.00%)	6 / 10 (60.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 10 (50.00%)	0 / 10 (0.00%)	2 / 10 (20.00%)
occurrences (all)	5	0	2
Dizziness			

subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
Thirst			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Flu like symptoms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 10 (30.00%)	1 / 10 (10.00%)	5 / 10 (50.00%)
occurrences (all)	3	1	5
Indigestion			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Weight loss			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Abdominal Cramps			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 September 2013	Submission to Research Ethics Committee of Protocol Version 1.1 which was created to address the comments in the Clinical Trial notice of non-acceptance of the initial clinical trial request.
17 June 2016	Updated documents due to additional dose of cholecalciferol being assessed in Part A dose confirmation: Protocol V3.2 20.10.2015 (Approved version 4.1 12/02/16) Translation of German SmPC (Address change of Copromoter) June 2014 GP Letter Part A Final 2.0 13.05.15 GP Letter Part B Final 2.0 13.05.15 Patient Card PART A 600,000 IU Final 2.0 13.05.15 Patient Card PART B Final 2.0 13.05.15 Vit D PIS_ICF Part A Final V2.0 15.05.15 Vit D PIS_ICF Part B Additional Samples Final Vit D PIS_ICF Part B Final v2.0 15.05.2015 Victoria Pharmaceuticals Product Specification 28.04.2015 Vitamin D diet questionnaire Final 1.0 02.10.2013 Viamin D falls questionnaire Final 1.0 02.10.2013 Vitamin D toxicity questionnaire Final 1.0 02.10.2013 MIA IMP V14 22.06.15
06 September 2016	Protocol updated to version 4.1 to incorporate MHRA comments from notice of non-acceptance of previous substantial amendment.
18 October 2017	Updated protocol to version 4.2 to allow a review of gastrointestinal adverse events and tolerability following the administration of the 600,000 IU liquid formulation.

Notes:

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.

Data analysis is descriptive statistics only. Results for the Part A dose confirmation only are presented. It was not possible to confirm a suitable dose of the current liquid formulation within the context of the current protocol.

Notes: