Clinical trial results:
A Randomized, Double-Blind, 12-Week, Placebo-Controlled Study Followed by a 12-Week Extension Phase Without Placebo to Evaluate the Efficacy and Safety of Oral VB-201 in Subjects with Mild to Moderate Ulcerative Colitis.

Summary

EudraCT number	2012-003974-18
Trial protocol	HU BG
Global end of trial date	28 November 2014

Results information

Result version number	v1 (current)
This version publication date	29 July 2016
First version publication date	29 July 2016

Trial information

Trial identification

Sponsor protocol code	VB-201-064

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Vascular Biogenics Ltd.
Sponsor organisation address	6 Jonathan Netanyahu St., Or Yehuda, Israel, 60376
Public contact	VBL, Vascular Biogenics Ltd., 972 36346450,
Scientific contact	VBL, Vascular Biogenics Ltd., 972 36346450,

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	02 February 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 November 2014
Global end of trial reached?	Yes
Global end of trial date	28 November 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- Safety Objective
• To examine the safety and tolerability of up to 24 weeks' treatment with VB-201 or placebo in subjects with Ulcerative Colitis
- Efficacy Objective
• Base Phase: To examine the effect of treatment with VB-201 80 mg twice daily, compared to placebo (initial 12 weeks) on measures of disease activity in subjects with Ulcerative Colitis.
• Extension Phase: To examine the effect of longer-term treatment with VB-201 (24 weeks) on measures of disease activity in subjects with Ulcerative Colitis.

Protection of trial subjects:

The trial was conducted in accordance with applicable national and international laws and regulations, the ICH-GCP guideline and the ethics principles that have their origins in the Declaration of Helsinki

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

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

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 23
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Poland: 88
Worldwide total number of subjects	112
EEA total number of subjects	112

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	107
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The first informed consent was given on 22 January 2013 and last patient last visit was on 28 November 2014.

Pre-assignment

Screening details:

Male or female sujects, ≥18 years of age, who had a diagnosis of active Ulcerative Colitis for at least 6 months prior to screening were selected according to the protocol inclusion and exclusion criteria.

Period 1

Period 1 title	Period 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Blinding implementation details:

The identity of the treatments was concealed by the use of trial medications that were all identical in packaging, labelling and schedule of administration. A combined batch number was generated. The IMP and the respective vehicle were indistinguishable in appearance, consistency and odor.

Arms

Are arms mutually exclusive?	Yes
Arm title	VB-201 (Arm A)

Arm description:

The VB-201 dose was 80 mg/day for the initial 2 weeks followed by 80 mg BID (160 mg/day) for 10 weeks.
After the initial 12 weeks, subjects entered the Extension Phase. During this phase, subjects continued dosing VB-201 at 80 mg BID.

Arm type	Experimental
Investigational medicinal product name	VB-201
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

All doses of trial medication were taken approximately 12 hours apart with food.

Arm title	Placebo & VB-201 (Arm B)

Arm description:

Subjects received placebo for weeks 1-12, followed by extension phase where subjects switched to dosing with VB-201 dosed at 80 mg/day for the initial 2 weeks followed by 80 mg BID during the final 10 weeks of the trial.

Arm type	Experimental
Investigational medicinal product name	VB-201
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

All doses of trial medication (placebo or VB-201) were taken approximately 12 hours apart with food.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

All doses of trial medication (placebo or VB-201) were taken approximately 12 hours apart with food..

Number of subjects in period 1	VB-201 (Arm A)	Placebo & VB-201 (Arm B)
Started	58	54
Completed	42	46
Not completed	16	8
Disease progression	1	-
Adverse event, non-fatal	6	3
Medical monitor decision	-	1
Lost to follow-up	1	-
Lack of cooperation	-	1
Lack of efficacy	5	1
Lack of motivation	3	1
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	VB-201 (Arm A)
Reporting group description:	
The VB-201 dose was 80 mg/day for the initial 2 weeks followed by 80 mg BID (160 mg/day) for 10 weeks. After the initial 12 weeks, subjects entered the Extension Phase. During this phase, subjects continued dosing VB-201 at 80 mg BID.	
Reporting group title	Placebo & VB-201 (Arm B)
Reporting group description:	
Subjects received placebo for weeks 1-12, followed by extension phase where subjects switched to dosing with VB-201 dosed at 80 mg/day for the initial 2 weeks followed by 80 mg BID during the final 10 weeks of the trial.	

Reporting group values	VB-201 (Arm A)	Placebo & VB-201 (Arm B)	Total
Number of subjects	58	54	112
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	39.57	40.54	
standard deviation	± 15.15	± 13.05	-
Gender categorical			
Units: Subjects			
Female	23	21	44
Male	35	33	68
Full modified Mayo Score			
Units: not applicable			
arithmetic mean	8	7.83	
standard deviation	± 1.4	± 1.58	-

End points

End points reporting groups

Reporting group title	VB-201 (Arm A)

Reporting group description:

The VB-201 dose was 80 mg/day for the initial 2 weeks followed by 80 mg BID (160 mg/day) for 10 weeks.
After the initial 12 weeks, subjects entered the Extension Phase. During this phase, subjects continued dosing VB-201 at 80 mg BID.

Reporting group title	Placebo & VB-201 (Arm B)

Reporting group description:

Subjects received placebo for weeks 1-12, followed by extension phase where subjects switched to dosing with VB-201 dosed at 80 mg/day for the initial 2 weeks followed by 80 mg BID during the final 10 weeks of the trial.

Primary: Remission Rates

End point title	Remission Rates

End point description:

End point type	Primary

End point timeframe:

Summary of remission rates by visit and treatment group, base and extension phase

End point values	VB-201 (Arm A)	Placebo & VB-201 (Arm B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	53		
Units: number of subjects				
remission at week 12	6	8		
no remission at week 12	51	45		
remission at week 24	13	10		
no remission at week 24	44	43		

Statistical analyses

Statistical analysis title	Remission at week 12 base phase

Statistical analysis description:

P-value chi-square test

Comparison groups	VB-201 (Arm A) v Placebo & VB-201 (Arm B)

Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4726
Method	Chi-squared

Statistical analysis title	Remission at week 24

Statistical analysis description:

Between group comparison week 12 Placebo (weeks 0-12) vs week 24 VB-201 80mg twice daily (weeks 0-24)

Comparison groups	VB-201 (Arm A) v Placebo & VB-201 (Arm B)
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3038
Method	Chi-squared

Primary: Safety

End point title	Safety[1]

End point description:

Summary of incidence of treatment emergent adverse events (TEAEs) for the study, for subjects in treatment Arms A& B. A full breakdown of adverse events (AEs) by study group and treatment administered (VB-201, placebo) is presented in the 'adverse events' section.

End point type	Primary

End point timeframe:

Entire duration of the study

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 safety is specified as a primary endpoint, descriptive statistics only are reported.

End point values	VB-201 (Arm A)	Placebo & VB-201 (Arm B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	54		
Units: number of subjects				
Subjects with any AEs	35	27		
Subjects with any Serious Adverse Events (SAEs)	5	6		
Subjects with any AEs leading to withdrawal	7	4		
Subjects with at least one Mild TEAE	29	13		
Subjects with at least one Moderate TEAE	11	17		
Subjects with at least one Severe TEAE	4	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary Efficacy

End point title	Secondary Efficacy

End point description:

End point type	Secondary

End point timeframe:

weeks 0-24 Arm A & weeks 12-24 Arm B.

End point values	VB-201 (Arm A)	Placebo & VB-201 (Arm B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	53		
Units: Total Modified Mayo score				
arithmetic mean (standard deviation)				
Week 12	6.33 (± 2.61)	5.64 (± 2.78)		
Week 24	5.58 (± 3.17)	4.57 (± 2.71)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Throughout the duration of the study (from screening visit to follow-up visit)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups	
Reporting group title	VB-201 (Arm A)
Reporting group description:	
The VB-201 dose was 80 mg/day for the initial 2 weeks followed by 80 mg BID (160 mg/day) for 10 weeks. After the initial 12 weeks, subjects entered the Extension Phase. During this phase, subjects continued dosing VB-201 at 80 mg twice daily..	
Reporting group title	placebo & VB-201 (Arm B)
Reporting group description:	
Subjects received placebo for weeks 1-12, followed by extension phase where subjects switched to dosing with VB-201 dosed at 80 mg/day for the initial 2 weeks followed by 80 mg twice daily during the final 10 weeks of the trial.	

Serious adverse events	VB-201 (Arm A)	placebo & VB-201 (Arm B)	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 58 (8.62%)	6 / 54 (11.11%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Ovarian cystectomy			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	4 / 58 (6.90%)	3 / 54 (5.56%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchopneumonia			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	VB-201 (Arm A)	placebo & VB-201 (Arm B)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 58 (56.90%)	24 / 54 (44.44%)	
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	3	0	
Mucosal haemorrhage			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	2 / 58 (3.45%)	1 / 54 (1.85%)	
occurrences (all)	2	1	
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Ovarian cyst			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Vaginal haemorrhage			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 58 (1.72%)	1 / 54 (1.85%)	
occurrences (all)	1	1	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 58 (1.72%)	1 / 54 (1.85%)	
occurrences (all)	1	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 58 (3.45%)	3 / 54 (5.56%)	
occurrences (all)	2	3	
Body temperature increased			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
C-reactive protein increased			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Eosinophil count increased			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Eosinophil percentage increased			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Haemoglobin abnormal			

subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Haemoglobin decreased			
subjects affected / exposed	1 / 58 (1.72%)	1 / 54 (1.85%)	
occurrences (all)	1	1	
Hepatic enzyme increased			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	2	0	
Lymphocyte count abnormal			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Lymphocyte percentage abnormal			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Mean cell haemoglobin concentration decreased			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Neutrophil count decreased			
subjects affected / exposed	3 / 58 (5.17%)	2 / 54 (3.70%)	
occurrences (all)	5	3	
Platelet count increased			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Protein urine			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
White blood cell count decreased			
subjects affected / exposed	2 / 58 (3.45%)	1 / 54 (1.85%)	
occurrences (all)	2	1	
White blood cell count increased			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			

Injury			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Limb injury			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Soft tissue injury			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 58 (3.45%)	0 / 54 (0.00%)	
occurrences (all)	8	0	
Headache			
subjects affected / exposed	6 / 58 (10.34%)	4 / 54 (7.41%)	
occurrences (all)	8	8	
Loss of consciousness			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Syncope			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	3	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 58 (6.90%)	2 / 54 (3.70%)	
occurrences (all)	4	2	
Iron deficiency anaemia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	3 / 58 (5.17%)	2 / 54 (3.70%)	
occurrences (all)	3	3	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 58 (3.45%)	4 / 54 (7.41%)	
occurrences (all)	9	4	
Abdominal pain upper			

subjects affected / exposed	1 / 58 (1.72%)	3 / 54 (5.56%)	
occurrences (all)	1	3	
Anal fissure			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	0 / 58 (0.00%)	2 / 54 (3.70%)	
occurrences (all)	0	2	
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Dyspepsia			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Frequent bowel movements			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Haemorrhoids			
subjects affected / exposed	0 / 58 (0.00%)	2 / 54 (3.70%)	
occurrences (all)	0	2	
Nausea			
subjects affected / exposed	8 / 58 (13.79%)	1 / 54 (1.85%)	
occurrences (all)	20	2	
Proctalgia			
subjects affected / exposed	1 / 58 (1.72%)	1 / 54 (1.85%)	
occurrences (all)	1	1	
Rectal prolapse			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	5 / 58 (8.62%)	1 / 54 (1.85%)	
occurrences (all)	17	2	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 58 (3.45%)	0 / 54 (0.00%)	
occurrences (all)	2	0	
Hyperhidrosis			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Onychoclasis			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	1 / 58 (1.72%)	1 / 54 (1.85%)	
occurrences (all)	1	3	
Rash pruritic			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Pollakiuria			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 58 (3.45%)	2 / 54 (3.70%)	
occurrences (all)	9	2	
Osteoporosis			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	2	0	
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Bronchitis			

subjects affected / exposed	2 / 58 (3.45%)	0 / 54 (0.00%)	
occurrences (all)	2	0	
Clostridium difficile infection			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Enterocolitis viral			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Lyme disease			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Nasopharyngitis			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Pharyngitis			
subjects affected / exposed	1 / 58 (1.72%)	1 / 54 (1.85%)	
occurrences (all)	1	1	
Pneumonia			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Respiratory tract infection			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	3 / 58 (5.17%)	1 / 54 (1.85%)	
occurrences (all)	3	1	
Urinary tract infection			
subjects affected / exposed	1 / 58 (1.72%)	1 / 54 (1.85%)	
occurrences (all)	1	1	
Viral infection			

subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	2	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Hypercholesterolaemia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Hyperkalaemia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Impaired fasting glucose			
subjects affected / exposed	1 / 58 (1.72%)	0 / 54 (0.00%)	
occurrences (all)	1	0	
Vitamin D deficiency			
subjects affected / exposed	0 / 58 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported