



Clinical trial results:

A phase IV, randomised, parallel study to compare a monthly administration of vitamin D3 (D-CURE®) to a daily administration of vitamin D3 (VISTA-D3®).

Summary

EudraCT number	2016-003755-29
Trial protocol	BE
Global end of trial date	13 March 2017

Results information

Result version number	v1 (current)
This version publication date	10 December 2017
First version publication date	10 December 2017

Trial information

Trial identification

Sponsor protocol code	D-CURE-IV-16-1
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Laboratoires SMB S.A.
Sponsor organisation address	Rue de la Pastorale, 26-28, Brussels, Belgium, 1080
Public contact	DEPARTEMENT CLINIQUE, LABORATOIRES SMB S.A, Dpt_Clinique@smb.be
Scientific contact	DEPARTEMENT CLINIQUE, LABORATOIRES SMB S.A, Dpt_Clinique@smb.be

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	03 July 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 March 2017
Global end of trial reached?	Yes
Global end of trial date	13 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine whether a cumulative dose of vitamin D3 produces the same effects on the serum concentration of 25-hydroxyvitamin D if it is given daily or monthly.

Protection of trial subjects:

For this study, no particular measure was taken to protect the trial subjects. Both study treatments (D-CURE and VISTA-D3) were already marketed in Belgium and then were well known by the most of participating subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 November 2016
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	Belgium: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	60
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted in one center in Belgium. The recruitment was adequate to meet the target of 60 subjects. After the screening visit, the subjects were randomized in one of the two groups of treatment. The study extended over one period of 75 days followed by a blood sampling 30 days after the last administration of vitamin D3.

Pre-assignment

Screening details:

- Obtain signed ICF
- Obtain demo data
- Perform a medical history & physical examination
- Take vital signs
- Review prior/concomitant medications
- Perform laboratory evaluations and pregnancy test
- Review inclusion/exclusion criteria
- Schedule the randomisation visit

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	D-CURE

Arm description:

The subjects received 2 ampoules of D-CURE of 25.000 IU each 25 days during 75 days.

Arm type	Experimental
Investigational medicinal product name	D-CURE 1 ml ampoule containing 25.000 IU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Two ampoules of 25.000 IU were taken every 25 days during a total period of 75 days (total dose = 150.000 IU)

Arm title	VISTA-D3
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Arm description:

The subjects received 1 melting tablet per day of VISTA-D3 of 2000 IU during 75 days consecutively.

Arm type	Active comparator
Investigational medicinal product name	VISTA-D3 melting tablet containing 2000 IU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet was to be taken each day during a total period of 75 days (total dose = 150.000 IU)

Number of subjects in period 1	D-CURE	VISTA-D3
Started	30	30
Completed	30	30

Baseline characteristics

Reporting groups

Reporting group title

Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	60	60	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	60	60	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	29.6		
standard deviation	± 8.6	-	
Gender categorical			
Units: Subjects			
Female	38	38	
Male	22	22	

End points

End points reporting groups

Reporting group title	D-CURE
Reporting group description: The subjects received 2 ampoules of D-CURE of 25.000 IU each 25 days during 75 days.	
Reporting group title	VISTA-D3
Reporting group description: The subjects received 1 melting tablet per day of VISTA-D3 of 2000 IU during 75 days consecutively.	

Primary: Mean change in serum 25(OH)D3 levels from baseline to D75.

End point title	Mean change in serum 25(OH)D3 levels from baseline to D75.
End point description:	
End point type	Primary
End point timeframe: Baseline (Day 1) and Day 75	

End point values	D-CURE	VISTA-D3		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: ng/ml				
arithmetic mean (standard deviation)	13.5 (± 5.5)	14.7 (± 7.0)		

Statistical analyses

Statistical analysis title	Mixed model
Statistical analysis description: Change from Baseline to day 75 in 25(OH)D3 serum level was compared between groups by a mixed model with group, Baseline value and group*Baseline as fixed factor and subject as random factors.	
Comparison groups	VISTA-D3 v D-CURE
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The AEs were recorded during the entire study period.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20
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Reporting groups

Reporting group title	D-CURE
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Reporting group description: -

Reporting group title	VISTA-D3
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Reporting group description: -

Serious adverse events	D-CURE	VISTA-D3	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	D-CURE	VISTA-D3	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 30 (63.33%)	15 / 30 (50.00%)	
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	
occurrences (all)	2	0	
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 30 (20.00%)	5 / 30 (16.67%)	
occurrences (all)	8	8	
General disorders and administration site conditions			
Influenza like illness			

subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	3 / 30 (10.00%) 3	
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	5 / 30 (16.67%) 5	3 / 30 (10.00%) 3	

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