



Clinical trial results:

Supplémentation en vitamine D chez des enfants et adolescents suivis en néphrologie pédiatrique: étude de l'efficacité du protocole habituel de service (cholécalférol) et de son impact sur la calciurie.

Summary

EudraCT number	2013-002710-13
Trial protocol	FR
Global end of trial date	17 October 2017

Results information

Result version number	v1 (current)
This version publication date	03 July 2021
First version publication date	03 July 2021

Trial information

Trial identification

Sponsor protocol code	2013-812
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02238418
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hospices Civils de Lyon
Sponsor organisation address	3 Quais des Célestins, Lyon, France, 69002
Public contact	Valérie Plattner, Hospices Civils de Lyon, +33 472115213, valerie.plattner@chu-lyon.fr
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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	15 July 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 October 2017
Global end of trial reached?	Yes
Global end of trial date	17 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluer l'efficacité du protocole habituel de service de supplémentation en vitamine D prescrite selon les recommandations (adaptée au poids des enfants et à la concentration de base en 25 OH vitamine D) chez des enfants suivis en néphrologie pédiatrique pour MRC, transplantation rénale ou syndrome néphrotique chronique.

Protection of trial subjects:

safety follow-up, signed consent by both parents

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 September 2014
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	France: 37
Worldwide total number of subjects	37
EEA total number of subjects	37

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)	18
Adolescents (12-17 years)	19
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients were recruited during their routine consultation

Period 1

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

Arms

Arm title	supplementation protocol
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Cholecalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in single-dose container
Routes of administration	Oral use

Dosage and administration details:

Patients above 60 kgs, 25-D levels:

<25 nmol/L Cholecalciferol 100,000 IU: 1 ampoule every 2 weeks during 2 months (400,000 IU= 4 ampoules in total)

25–50 nmol/L Cholecalciferol 100,000 IU: 1 ampoule every 2 weeks during 6 weeks (300,000 IU= 3 ampoules in total)

50–75 nmol/L Cholecalciferol 100,000 IU: 1 ampoule every 2 weeks during 4 weeks (200,000 IU= 2 ampoules in total)

Patients between 20 and 60 kgs, 25-D levels:

<25 nmol/L Cholecalciferol 100,000 IU: 1 ampoule every month during 2 months (200,000 IU= 2 ampoules in total)

From 25 to 50 nmol/L Cholecalciferol 100,000 IU: 1 ampoule every 6 weeks during 2 months (200,000 IU=2 ampoules in total)

From 50 to 75 nmol/L Cholecalciferol 100,000 IU: 1 single ampoule

Patients below 20 kgs with 25-D levels below 75 nmol/L

Cholecalciferol 100,000 IU: 1 single ampoule

Number of subjects in period 1	supplementation protocol
Started	37
Completed	35
Not completed	2
Protocol deviation	2

Baseline characteristics

Reporting groups

Reporting group title	Overall
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Reporting group description: -

Reporting group values	Overall	Total	
Number of subjects	37	37	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
median	10.9		
full range (min-max)	3.2 to 18.2	-	
Gender categorical			
Units: Subjects			
Female	16	16	
Male	21	21	
Weight			
Units: kg			
median	35.6		
full range (min-max)	11.9 to 81	-	
BMI			
Units: kg/m ²			
median	17.2		
full range (min-max)	13.3 to 30.1	-	
Age at transplantation			
Units: years			
median	8.6		
full range (min-max)	1.3 to 17.3	-	
eGFR			
Units: ml/min/1.73m ²			
median	85		
full range (min-max)	13 to 198	-	
Height			
Units: cm			
median	137		
full range (min-max)	92 to 181	-	

End points

End points reporting groups

Reporting group title	supplementation protocol
Reporting group description: -	

Primary: 25 OH vitamin D

End point title	25 OH vitamin D ^[1]
End point description: evolution at baseline and 2 months after vitamin supplementation	
End point type	Primary
End point timeframe: At baseline and at 2 months	

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: The system does not allow for statistical analysis for studies with a single treatment arm. $p < 0.05$

End point values	supplementation protocol			
Subject group type	Reporting group			
Number of subjects analysed	35			
Units: nmol/L				
median (full range (min-max))				
At baseline	50 (12 to 75)			
At 2 months	76 (54 to 157)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

2 months

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18
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Reporting groups

Reporting group title	Vitamin D supplementation
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Reporting group description: -

Serious adverse events	Vitamin D supplementation		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 35 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Vitamin D supplementation		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 35 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No AE reported in this study

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 November 2014	Add of biocollections Ethnic origin collection
20 October 2015	Recruitment period extension

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/31873802>