Clinical trial results:
Controlled, randomized, four-arm comparative, open label, multi-centric trial to compare the efficacy and safety parameters of the once-a-week or once-a-month administered 7000 IU, or 30000 IU vitamin D (cholecalciferol) to a 1000 IU dosage applied daily in vitamin D deficient patients

Summary

EudraCT number	2012-005232-29
Trial protocol	HU
Global end of trial date	11 December 2013
Results information	
Result version number	v1 (current)
This version publication date	23 October 2021
First version publication date	23 October 2021
Summary attachment (see zip file)	Clinical Study Summary PAT12-730DS (Clinical Study Summary PAT12-730DS.docx)

Trial information

Trial identification	
Sponsor protocol code	PAT12-730DS
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Pharma Patent Kft.
Sponsor organisation address	Szentlászlói út 44., Szentendre, Hungary, 2000
Public contact	Iroda-törzskönyvezés, Pharma Patent Kft, +36 1630 6182, clinical@pharmapatent.hu
Scientific contact	Iroda-törzskönyvezés, Pharma Patent Kft, +36 1630 6182, clinical@pharmapatent.hu

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	14 January 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 December 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Comparison efficacy by 25OHD and safety parameters of a daily single dose of 1000 IU to a once-a week or once-a month administered 7000 IU or 30000 IU vitamin D, respectively.

Protection of trial subjects:

Specific measures were not needed. The only intervention during the course of study was blood sample collection. Patients were informed in details about the possible side effect and all the contacts of the medical support.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 February 2013
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	Hungary: 89
Worldwide total number of subjects	89
EEA total number of subjects	89

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)	70
From 65 to 84 years	19
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

D vitamin level <20ng/ml, Lab tests for 25(OH)D, seCa, PTH, Urine analysis, Lab blood test and routine chemistry. Screened 140 subjects, 89 enrolled.
Main reason for exclusion: high D vitamine level.

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	Group "A"

Arm description:

1000 IU kolekalciferol (Vitamin D3), 1000 IU once a day, per os

Arm type	Active comparator
Investigational medicinal product name	1000 IU kolekalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1000 IU once a day, per os

Arm title	Group "B"

Arm description:

7000 IU kolekalciferol (Vitamin D3), 7000 IU once a week, per os

Arm type	Active comparator
Investigational medicinal product name	7000 IU kolekalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

7000 IU once a week, per os

Arm title	Group "C"

Arm description:

30000 IU kolekalciferol (Vitamin D3), 30000 IU once a month, per os

Arm type	Active comparator
Investigational medicinal product name	30000 IU kolekalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

30000 IU once a month, per os

Investigational medicinal product name	30000 IU kolekalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:
30000 IU once a week, per os

Arm title	Group "D"

Arm description:
30000 IU kolekalciferol (Vitamin D3), 30000 IU once a week, per os

Arm type	Active comparator
Investigational medicinal product name	30000 IU kolekalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:
30000 IU once a week, per os

Number of subjects in period 1	Group "A"	Group "B"	Group "C"
Started	22	23	22
Completed	21	20	20
Not completed	1	3	2
Consent withdrawn by subject	-	1	2
Lost to follow-up	1	2	-

Number of subjects in period 1	Group "D"
Started	22
Completed	21
Not completed	1
Consent withdrawn by subject	1
Lost to follow-up	-

Baseline characteristics

End points

End points reporting groups	
Reporting group title	Group "A"
Reporting group description: 1000 IU kolekalciferol (Vitamin D3), 1000 IU once a day, per os	
Reporting group title	Group "B"
Reporting group description: 7000 IU kolekalciferol (Vitamin D3), 7000 IU once a week, per os	
Reporting group title	Group "C"
Reporting group description: 30000 IU kolekalciferol (Vitamin D3), 30000 IU once a month, per os	
Reporting group title	Group "D"
Reporting group description: 30000 IU kolekalciferol (Vitamin D3), 30000 IU once a week, per os	

Primary: Changes in 25(OH)D versus to baseline in each group	
End point title	Changes in 25(OH)D versus to baseline in each group
End point description:	
End point type	Primary
End point timeframe: 90 days	

End point values	Group "A"	Group "B"	Group "C"	Group "D"
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	20	21
Units: ng/ml	21	20	20	21

Statistical analyses

Statistical analysis title	ANOVA
Statistical analysis description: ANOVA and paired test of Dunnett.	
Comparison groups	Group "B" v Group "C" v Group "D" v Group "A"
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	≤ 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	28

Confidence interval	
level	95 %
sides	2-sided
lower limit	27
upper limit	30

Notes:

[1] - 1. and 2. groups comparison level 81.5%
1. and 3. groups comparison level 80.6%
1. and 4. groups comparison level 99.5%

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Recording of sign of adverse event were done by each visit and in between visit by the phone follow-up visits.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	15

Reporting groups	
Reporting group title	D group
Reporting group description: -	
Reporting group title	A group
Reporting group description: -	
Reporting group title	B group
Reporting group description: -	
Reporting group title	C group
Reporting group description: -	

Serious adverse events	D group	A group	B group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 23 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	C group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	D group	A group	B group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 22 (9.09%)	3 / 22 (13.64%)	5 / 23 (21.74%)
Endocrine disorders			

Laboratory disorder subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2	3 / 22 (13.64%) 3	5 / 23 (21.74%) 5

Non-serious adverse events	C group		
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 22 (4.55%)		
Endocrine disorders Laboratory disorder subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 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