Clinical trial results:
Investigate the differences between treating Chronic Kidney Disease - Mineral and Bone Disorder with an iron-containing phosphate binder or a calcium-containing phosphate binder in Chronic Kidney Disease stage 3-5.

Summary

EudraCT number	2017-002095-10
Trial protocol	DK
Global end of trial date	14 November 2019

Results information

Result version number	v1 (current)
This version publication date	02 January 2021
First version publication date	02 January 2021

Trial information

Trial identification

Sponsor protocol code	MV-2-2017

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medicinsk forskning
Sponsor organisation address	Lægårdvej 12, Holstebro, Denmark, 7500
Public contact	Marie Houmaa Vrist, Universitetsklinik for Nyresygdomme og Blodtryksforhøjelse, Regionshospitalet Holstebro, +45 78436585, Jesper.Noergaard.Bech@vest.rm.dk
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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	09 December 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 November 2019
Global end of trial reached?	Yes
Global end of trial date	14 November 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To investigate whether treatment with an iron- or calcium-containing phosphate binder can affect differently the results from 18F-NaF PET/CT, bALP, osteocalcin, FGF23 og OPG/RANKL ratio. Differences in the stiffness of blood vessel assessed with applanation tonometry. Finally, we investigate changes in calcium score (TBR) and iron status

Protection of trial subjects:

Blood samples every second week

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 January 2018
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	Denmark: 27
Worldwide total number of subjects	27
EEA total number of subjects	27

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)	15
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Deltagerne er rekrutterret til ambulatoriet nyremedicisk Dagafsnit, holstebro Regionshospital, danmark

Pre-assignment

Screening details:

30-80 years and CKD stage 3-5d

Period 1

Period 1 title	Behandlingsperiode 1
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Velphoro

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Velphoroo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

Treatment with SO or CC aimed to reduce p-phospate to < 1.8 mmol/L (CC up to 3600 mg/day; SO up to 3000 mg/day). However, if dose escalation did not reduce phosphate levels < 1.8 mmol/L, and the phosphate levels remained stable, further dose escalations were not performed. Treatment periods were 8 weeks however, if phosphorus level was not stable, the treatment was continued, though maximum 15 weeks. The treatment periods were separated by at minimum of a 2-week washout period. A run-in period of 2 weeks was applied if the patient already was treated with a phosphate binder.

Arm title	Unikalk basic

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Unikalk basic
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Treatment with SO or CC aimed to reduce p-phospate to < 1.8 mmol/L (CC up to 3600 mg/day; SO up to 3000 mg/day). However, if dose escalation did not reduce phosphate levels < 1.8 mmol/L, and the phosphate levels remained stable, further dose escalations were not performed. Treatment periods were 8 weeks however, if phosphorus level was not stable, the treatment was continued, though maximum 15 weeks. The treatment periods were separated by at minimum of a 2-week washout period. A run-in period of 2 weeks was applied if the patient already was treated with a phosphate binder.

Number of subjects in period 1	Velphoro	Unikalk basic
Started	13	13
Completed	8	9
Not completed	5	4
Consent withdrawn by subject	2	1
Physician decision	-	2
Adverse event, non-fatal	3	-
Protocol deviation	-	1

Period 2

Period 2 title	Behandlingsperiode 2
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Velphoro

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Velphoro
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

Treatment with SO or CC aimed to reduce p-phospate to < 1.8 mmol/L (CC up to 3600 mg/day; SO up to 3000 mg/day). However, if dose escalation did not reduce phosphate levels < 1.8 mmol/L, and the phosphate levels remained stable, further dose escalations were not performed. Treatment periods were 8 weeks however, if phosphorus level was not stable, the treatment was continued, though maximum 15 weeks. The treatment periods were separated by at minimum of a 2-week washout period. A run-in period of 2 weeks was applied if the patient already was treated with a phosphate binder.

Arm title	unikalk

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Unikalk basic
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Treatment with SO or CC aimed to reduce p-phospate to < 1.8 mmol/L (CC up to 3600 mg/day; SO up to 3000 mg/day). However, if dose escalation did not reduce phosphate levels < 1.8 mmol/L, and the phosphate levels remained stable, further dose escalations were not performed. Treatment periods were 8 weeks however, if phosphorus level was not stable, the treatment was continued, though maximum 15 weeks. The treatment periods were separated by at minimum of a 2-week washout period. A run-in period of 2 weeks was applied if the patient already was treated with a phosphate binder.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Resultaterne fra de deltager der ikke har gennemført begge behandlingsperioder er ikke analyseret og derfor er baseline mest repræsentativt uden disse for at se om grupperne er ens

Number of subjects in period 2[2]	Velphoro	unikalk
Started	9	8
Completed	7	7
Not completed	2	1
Consent withdrawn by subject	-	1
Adverse event, non-fatal	1	-
Protocol deviation	1	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: En deltager bliver inkluderet men ønsker allerede inden han er randomiseret alligevel ikke deltagelse.

Baseline characteristics

Reporting groups	
Reporting group title	Velphoro
Reporting group description: -	
Reporting group title	unikalk
Reporting group description: -	

Reporting group values	Velphoro	unikalk	Total
Number of subjects	9	8	17
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			
arithmetic mean	61	64	
standard deviation	± 4.2	± 8.3	-
Gender categorical Units: Subjects			
Female	2	4	6
Male	7	4	11

End points

End points reporting groups

Reporting group title	Velphoro
Reporting group description: -	
Reporting group title	Unikalk basic
Reporting group description: -	
Reporting group title	Velphoro
Reporting group description: -	
Reporting group title	unikalk
Reporting group description: -	

Primary: Ki (lumbal)

End point title	Ki (lumbal)[1]
End point description:	
End point type	Primary
End point timeframe:	
end of 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: Der er ikke valgt statistiske analyser, da data fra dette projekt er kombineret med et lignende projekt for at opnå brugbare resultater. Dette vil blive publiceret i en kommende artikel.

End point values	Velphoro	unikalk		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: ml/min-1/ml-1				
arithmetic mean (standard deviation)	0.027 (± 0.01)	0.030 (± 0.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: osteocalcin

End point title	osteocalcin
End point description:	
End point type	Secondary
End point timeframe:	
end of study	

End point values	Velphoro	unikalk		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: ug/L				
arithmetic mean (standard deviation)	149 (± 180)	134 (± 174)		

Statistical analyses

No statistical analyses for this end point

Secondary: bALP

End point title	bALP

End point description:

End point type	Secondary

End point timeframe:
end of study

End point values	Velphoro	unikalk		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: µg/l				
arithmetic mean (standard deviation)	17.13 (± 6.4)	22.8 (± 11.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Fra første scanning til 48 timer efter sidste scanning	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	21
Reporting groups	
Reporting group title	Velphoro

Reporting group description: -

Serious adverse events	Velphoro		
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	0		

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

Non-serious adverse events	Velphoro		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 22 (31.82%)		
Gastrointestinal disorders			
kvalme, opkast, forstoppelse eller mavesmerter			
subjects affected / exposed	7 / 22 (31.82%)		
occurrences (all)	7		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Resultaterne fra dette studie vil blive publiseret sammen med da fra et tilsvarende studie med dialysepatienter, så antallet af deltager bliver højere og studiet dermed opnår nok power.

Notes: