



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 dialysis patients.

Summary

EudraCT number	2017-002096-26
Trial protocol	DK
Global end of trial date	20 August 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-3-2017
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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
Scientific contact	Marie Houmaa Vrist, Universitetsklinik for Nyresygdomme og Blodtryksforhøjelse, Regionshospitalet Holstebro, +45 78436585, Jesper.Noergaard.Bech@vest.rm.dk

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	06 January 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 August 2019
Global end of trial reached?	Yes
Global end of trial date	20 August 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:

blodprøve kontroller hver 14. dag

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2017
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: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	5
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Deltagerne er fundet i dialyseafsnitte på regionshospitalet Holstebro

Pre-assignment

Screening details:

dialyse i mere end 3 mdr, alder mellem 18 - 75

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	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-phosphate 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. Fig. 2 shows the study design.

Arm title	Unikalk basic
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Unikalk basico
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-phosphate 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. Fig. 2 shows the study design.

Number of subjects in period 1	Velphoro	Unikalk basic
Started	4	4
Completed	4	4

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-phosphate 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. Fig. 2 shows the study design.

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-phosphate 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. Fig. 2 shows the study design.

Notes:

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

Justification: Resultater fra dette studie er set på som et overkrydset studie og er desuden slået

sommen med et tilsvarende studie med ckd3-5 patienter for at opnå brugbare resultater

Number of subjects in period 2 ^[2]	Velphoro	Unikalk basic
Started	4	4
Completed	4	4

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: To deltager gik ud af studiet før randomisering. Én trak sit samtykke tilbage og én fik apopleksi og blev derfor ekskluderet.

Baseline characteristics

Reporting groups

Reporting group title	Behandlingsperiode 2
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Reporting group description: -

Reporting group values	Behandlingsperiode 2	Total	
Number of subjects	8	8	
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	61.6		
standard deviation	± 11.9	-	
Gender categorical Units: Subjects			
Female	1	1	
Male	7	7	

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 basic
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 var ganske få data i dette projekt, hvorfor data er behandlet sammen med et lignende projekt for at opnå brugbare data.

End point values	Velphoro	Unikalk basic		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: ml/min-1/ml-1				
arithmetic mean (standard deviation)	0.028 (± 0.01)	0.028 (± 0)		

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 basic		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	4		
Units: ug/L				
arithmetic mean (standard deviation)	159 (± 99.3)	126 (± 89.6)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Fra indgift af første forsøgs-medicin til 48 timer efter indgift af sidste forsøgs-medicin.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21
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Reporting groups

Reporting group title	Velphoro
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Reporting group description: -

Serious adverse events	Velphoro		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (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	1 / 8 (12.50%)		
Gastrointestinal disorders			
diarre			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	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