



## Clinical trial results:

### 18F-NaF PET/CT in combination with biomarkers for the classification of renal osteodystrophy in chronic kidney disease

#### Summary

EudraCT number	2016-005160-34
Trial protocol	DK
Global end of trial date	03 July 2020

#### Results information

Result version number	v1 (current)
This version publication date	02 January 2021
First version publication date	02 January 2021
Summary attachment (see zip file)	summary (summary.docx)

#### Trial information

##### Trial identification

Sponsor protocol code	MV-1-2017
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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, Universitetsklinikken for Nyresygdomme og Blodtryksforhøjelse, +45 78436585, marvri@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:

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**Results analysis stage**

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Analysis stage	Final
Date of interim/final analysis	31 August 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 June 2019
Global end of trial reached?	Yes
Global end of trial date	03 July 2020
Was the trial ended prematurely?	Yes

Notes:

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**General information about the trial**

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Main objective of the trial:

To investigate 18 F-NaF PET/CT in combination with biomarkers for classification of subtypes of renal osteodystrophy in patients treated with hemodialysis. This is compared to the golden standard (bone biopsy with double tetracycline labeling).

Protection of trial subjects:

Coagulation blood samples were analyzed before bone biopsy

Background therapy:

Tetracycline 500mg two day twice with a 10 days interval.

Evidence for comparator: -

Actual start date of recruitment	02 January 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Denmark: 34
Worldwide total number of subjects	34
EEA total number of subjects	34

Notes:

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**Subjects enrolled per age group**

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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)	19
From 65 to 84 years	15
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Patients from the department of Nephrology, Høstebro Hospital and Aalborg Hospital, Denmark

### Pre-assignment

Screening details:

informed consent

dialysis more than 3 month

### Period 1

Period 1 title	scan and bone biopsy (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

### Arms

<b>Arm title</b>	A one arm study
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	sodium fluoride F 18
Investigational medicinal product code	PR1
Other name	NaF, 18F-NaF
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

150 MBq once at scan start

<b>Number of subjects in period 1</b>	A one arm study
Started	34
scan data available	17
bone biopsy data available	17
Completed	17
Not completed	17
Consent withdrawn by subject	10
Lost to follow-up	2
Protocol deviation	5

## Baseline characteristics

### Reporting groups

Reporting group title	A one arm study
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Reporting group description: -

Reporting group values	A one arm study	Total	
Number of subjects	34	34	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	62.5 ± 10.1	-	
Gender categorical Units: Subjects			
Female	9	9	
Male	25	25	

## End points

### End points reporting groups

Reporting group title	A one arm study
Reporting group description: -	

### Primary: Ki

End point title	Ki <sup>[1]</sup>
End point description: Ki measured from 18-NaF PET/CT, patlak single point, semi-population input function	
End point type	Primary
End point timeframe: After completed the 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: It is a one arm study. I will like you to look at the upcoming paper for statistical analyses

<b>End point values</b>	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: ml-1/min/ml-1				
arithmetic mean (standard deviation)	0.0344 (± 0.008)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Ac.F

End point title	Ac.F
End point description:	
End point type	Secondary
End point timeframe:	
End of study	

<b>End point values</b>	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: years-1				
arithmetic mean (standard deviation)	0.72 ( $\pm$ 0.67)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: BFR/BS

End point title	BFR/BS
End point description:	
End point type	Secondary
End point timeframe:	
end of study	

<b>End point values</b>	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: years				
arithmetic mean (standard deviation)	33.24 ( $\pm$ 30.96)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mlt.

End point title	Mlt.
End point description:	
End point type	Secondary
End point timeframe:	
end of study	

<b>End point values</b>	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: days				
arithmetic mean (standard deviation)	39 (± 53)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: BV/TV

End point title	BV/TV
End point description:	
End point type	Secondary
End point timeframe:	
end of study	

<b>End point values</b>	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: %				
number (not applicable)	12.3			

### 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	

<b>End point values</b>	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: µg/l				
arithmetic mean (standard deviation)	21.6 (± 7.53)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: FGF23

End point title	FGF23
End point description:	
End point type	Secondary
End point timeframe:	
end of study	

<b>End point values</b>	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: pg/mL				
arithmetic mean (standard deviation)	4542 (± 4075)			

### 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	

<b>End point values</b>	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: µg/				
arithmetic mean (standard deviation)	170 (± 89)			

### Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

From first tablet prescription before bone biopsy until sutures removed.

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	All subjects
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Reporting group description: -

Serious adverse events	All subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 34 (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: The tracer <sup>18</sup>F-NaF is known well tolerated for many years applied with other scan methods

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported