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

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
Scientific contact	Jesper N. Bech, Universitetsklinikken for Nyresygdomme og Blodtryksforhøjelse, +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	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:

General information about the trial

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:

Population of trial subjects

Subjects enrolled per country

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

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

Subject disposition

Recruitment

Recruitment details:

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

Pre-assignment

Screening details:

informed constent
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

Arm title	A one arm study

Arm description: -

Arm type	Experimental
Investigational medicinal product name	sodium fluride 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

Number of subjects in period 1	A one arm study
Started	34
scan data avaiable	17
bone biopsy data availible	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

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[1]

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 upcomning paper for statistical analyses

End point values	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

End point values	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: years-1				
arithmetic mean (standard deviation)	0.72 (± 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

End point values	A one arm study			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: years				
arithmetic mean (standard deviation)	33.24 (± 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

End point values	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

End point values	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

End point values	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

End point values	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

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

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From first tablet prescription before bone biopsy until sutures removed.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21

Reporting groups

Reporting group title	All subjects

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 18F-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

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported