Clinical trial results:
Intravenous iron in patients with heart failure and reduced ejection fraction (HFREF) plus iron deficiency:
Effects upon phosphate and FGF23 metabolism

Summary

EudraCT number	2016-004147-37
Trial protocol	DE
Global end of trial date	25 October 2017

Results information

Result version number	v1 (current)
This version publication date	19 March 2022
First version publication date	19 March 2022

Trial information

Trial identification

Sponsor protocol code	16-047

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Center for Translational & Clinical Research Aachen (CTC-A)
Sponsor organisation address	Pauwelsstraße 30, Aachen, Germany, 52074
Public contact	Center for Translational & Clinical Research Aachen (CTC-A), Universitätsklinikum RWTH Aachen, 0049 2418080092, ctc-a-spoqs@ukaachen.de
Scientific contact	Center for Translational & Clinical Research Aachen (CTC-A), Universitätsklinikum RWTH Aachen, 0049 2418080092, ctc-a-spoqs@ukaachen.de

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	26 January 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 October 2017
Global end of trial reached?	Yes
Global end of trial date	25 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Effects of ferric carboxymaltose single HD (1000 mg) infusion upon FGF23 in patients with isolated HFREF compared to patients with HFREF+CKD (all pts with iron deficiency). This study aims at identification of the optimal target population for a follow-up ("main") study.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation of Good Clinical Practice, the principles of the Declaration of Helsinki, as well as other applicable local ethical and legal requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 March 2017
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	Germany: 23
Worldwide total number of subjects	23
EEA total number of subjects	23

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)	10
From 65 to 84 years	12
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Recruitment and treatment of subjects was performed in one trial center. Overall 23 subjects were enrolled and randomized in the clinical trial in the timeframe from 13.03.2017 till 25.10.2017.

Pre-assignment

Screening details:

Overall 51 subjects were screened in one trial center. Of those 51 subjects screened, 23 subjects met the inclusion and exclusion criteria and were enrolled.

Period 1

Period 1 title	Day 0 pre-infusion
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Chronic Kidney Disease

Arm description:

Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Arm title	Non Chronic Kidney Disease

Arm description:

Non Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Number of subjects in period 1	Chronic Kidney Disease	Non Chronic Kidney Disease
Started	12	11
Completed	12	11

Period 2	
Period 2 title	Day 0 post-infusion
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Chronic Kidney Disease

Arm description:
Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Arm title	Non Chronic Kidney Disease

Arm description:
Non Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Number of subjects in period 2	Chronic Kidney Disease	Non Chronic Kidney Disease
Started	12	11
Completed	12	11

Period 3	
Period 3 title	Day 1
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Chronic Kidney Disease

Arm description:
Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Arm title	Non Chronic Kidney Disease

Arm description:
Non Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Number of subjects in period 3	Chronic Kidney Disease	Non Chronic Kidney Disease
Started	12	11
Completed	12	11

Period 4	
Period 4 title	Day 7
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Chronic Kidney Disease

Arm description:
Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Arm title	Non Chronic Kidney Disease

Arm description:
Non Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Number of subjects in period 4	Chronic Kidney Disease	Non Chronic Kidney Disease
Started	12	11
Completed	12	11

Period 5	
Period 5 title	Day 14
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Chronic Kidney Disease

Arm description:
Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Arm title	Non Chronic Kidney Disease

Arm description:
Non Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Number of subjects in period 5	Chronic Kidney Disease	Non Chronic Kidney Disease
Started	12	11
Completed	12	11

Period 6	
Period 6 title	Day 28
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Chronic Kidney Disease

Arm description:
Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Arm title	Non Chronic Kidney Disease

Arm description:
Non Chronic Kidney Disease

Arm type	Experimental
Investigational medicinal product name	Iron(III) carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Infusion of 1000 mg Iron(III)-carboxymaltose (Ferrinject) via intravenous injection

Number of subjects in period 6	Chronic Kidney Disease	Non Chronic Kidney Disease
Started	12	11
Completed	12	11

Baseline characteristics

Reporting groups	
Reporting group title	Day 0 pre-infusion

Reporting group description: -

Reporting group values	Day 0 pre-infusion	Total	
Number of subjects	23	23	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 66.7 ± 12.26	 -	
Gender categorical Units: Subjects			
Female	11	11	
Male	12	12	

End points

End points reporting groups

Reporting group title	Chronic Kidney Disease
Reporting group description: Chronic Kidney Disease	
Reporting group title	Non Chronic Kidney Disease
Reporting group description: Non Chronic Kidney Disease	
Reporting group title	Chronic Kidney Disease
Reporting group description: Chronic Kidney Disease	
Reporting group title	Non Chronic Kidney Disease
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Reporting group description: Non Chronic Kidney Disease	
Reporting group title	Chronic Kidney Disease
Reporting group description: Chronic Kidney Disease	
Reporting group title	Non Chronic Kidney Disease
Reporting group description: Non Chronic Kidney Disease	
Subject analysis set title	Baseline CKD
Subject analysis set type	Sub-group analysis
Subject analysis set description: Patients with chronic kidney disease at baseline	
Subject analysis set title	Baseline non-CKD
Subject analysis set type	Sub-group analysis
Subject analysis set description: Patients without chronic kidney disease at baseline.	

Primary: intact FGF23 (iFGF23) - Day 0 pre-infusion	
End point title	intact FGF23 (iFGF23) - Day 0 pre-infusion
End point description:	

End point type	Primary
End point timeframe:	
Day 0 pre-infusion	

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	12	11	12	11
Units: pg / ml				
arithmetic mean (standard deviation)	214.2 (± 188.6)	17.28 (± 11.01)	214.2 (± 188.6)	17.28 (± 11.01)

Statistical analyses

Statistical analysis title	Analysis iFGF23-CKD - Day 0 pre-infusion
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis iFGF23-non-CKD - Day 0 pre-infusion
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Primary: intact FGF23 (iFGF23) - Day 0 post-infusion	
End point title	intact FGF23 (iFGF23) - Day 0 post-infusion
End point description:	

End point type	Primary
End point timeframe:	
Day 0 post-infusion	

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	12	11	12	11
Units: pg / ml				
arithmetic mean (standard deviation)	228.4 (± 210.1)	10.64 (± 11.85)	214.2 (± 188.6)	17.28 (± 11.01)

Statistical analyses

Statistical analysis title	Analysis iFGF23-CKD - Day 0 post-infusion
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis iFGF23-non-CKD - Day 0 post-infusion
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Primary: intact FGF23 (iFGF23) - Day 1

End point title	intact FGF23 (iFGF23) - Day 1

End point description:

End point type	Primary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	12	11	12	11
Units: pg / ml				
arithmetic mean (standard deviation)	384.6 (± 316.2)	178.9 (± 131.6)	214.2 (± 188.6)	17.28 (± 11.01)

Statistical analyses

Statistical analysis title	Analysis iFGF23-CKD - Day 1
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis iFGF23-non-CKD - Day 1
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	generalized least squares linear model

Primary: intact FGF23 (iFGF23) - Day 7

End point title	intact FGF23 (iFGF23) - Day 7

End point description:

End point type	Primary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11[1]	11	12	11
Units: pg / ml				
arithmetic mean (standard deviation)	289.7 (± 335.3)	126.5 (± 80.46)	214.2 (± 188.6)	17.28 (± 11.01)

Notes:
[1] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis iFGF23-CKD - Day 7
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis iFGF23-non-CKD - Day 7
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	generalized least squares linear model

Primary: intact FGF23 (iFGF23) - Day 14	
End point title	intact FGF23 (iFGF23) - Day 14

End point description:

End point type	Primary

End point timeframe:
Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	9[2]	10[3]	12	11
Units: pg / ml				
arithmetic mean (standard deviation)	222.7 (± 168.75)	65.9 (± 56.03)	214.2 (± 188.6)	17.28 (± 11.01)

Notes:
[2] - 3 missing data
[3] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis iFGF23-CKD - Day 14
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis iFGF23-non-CKD - Day 14
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	generalized least squares linear model

Primary: intact FGF23 (iFGF23) - Day 28

End point title	intact FGF23 (iFGF23) - Day 28

End point description:

End point type	Primary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	10[4]	10[5]	12	11
Units: pg / ml				
arithmetic mean (standard deviation)	169.03 (± 176.32)	24.53 (± 23.45)	214.2 (± 188.6)	17.28 (± 11.01)

Notes:

[4] - 2 missing data

[5] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis iFGF23-CKD - Day 28
Comparison groups	Chronic Kidney Disease v Baseline CKD

Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis iFGF23-non-CKD - Day 28
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Primary: c-term FGF23 (cFGF23) - Day 0 pre-infusion

End point title	c-term FGF23 (cFGF23) - Day 0 pre-infusion

End point description:

End point type	Primary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11[6]	11	11[7]	11
Units: RU / ml				
arithmetic mean (standard deviation)	805.6 (± 535.8)	302.5 (± 464.8)	805.6 (± 535.8)	302.5 (± 464.8)

Notes:

[6] - 1 missing data

[7] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis cFGF23-CKD - Day 0 pre-infusion
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis cFGF23-non-CKD - Day 0 pre-infusion
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Primary: c-term FGF23 (cFGF23) - Day 0 post-infusion	
End point title	c-term FGF23 (cFGF23) - Day 0 post-infusion
End point description:	
End point type	Primary
End point timeframe:	
Day 0 post-infusion	

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11[8]	11	11[9]	11
Units: RU / ml				
arithmetic mean (standard deviation)	751.1 (± 493.2)	329.9 (± 501.5)	805.6 (± 535.8)	302.5 (± 464.8)

Notes:

[8] - 1 missing data

[9] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis cFGF23-CKD - Day 0 post-infusion
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis cFGF23-non-CKD - Day 0 post-infusion
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD

Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Primary: c-term FGF23 (cFGF23) - Day 1

End point title	c-term FGF23 (cFGF23) - Day 1

End point description:

End point type	Primary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11[10]	11	11[11]	11
Units: RU / ml				
arithmetic mean (standard deviation)	756.8 (± 515.9)	342.1 (± 424.2)	805.6 (± 535.8)	302.5 (± 464.8)

Notes:

[10] - 1 missing data

[11] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis cFGF23-CKD - Day 1
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis cFGF23-non-CKD - Day 1
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Primary: c-term FGF23 (cFGF23) - Day 7

End point title	c-term FGF23 (cFGF23) - Day 7

End point description:

End point type	Primary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	10[12]	11	11[13]	11
Units: RU / ml				
arithmetic mean (standard deviation)	693.7 (± 499.1)	178.2 (± 154.4)	805.6 (± 535.8)	302.5 (± 464.8)

Notes:

[12] - 2 missing data

[13] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis cFGF23-CKD - Day 7
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis cFGF23-non-CKD - Day 7
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Primary: c-term FGF23 (cFGF23) - Day 14

End point title	c-term FGF23 (cFGF23) - Day 14

End point description:

End point type	Primary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	9[14]	10[15]	11[16]	11
Units: RU / ml				
arithmetic mean (standard deviation)	605.4 (± 486.11)	83.5 (± 36.12)	805.6 (± 535.8)	302.5 (± 464.8)

Notes:

[14] - 3 missing data

[15] - 1 missing data

[16] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis cFGF23-CKD - Day 14
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis cFGF23-non-CKD - Day 14
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Primary: c-term FGF23 (cFGF23) - Day 28

End point title	c-term FGF23 (cFGF23) - Day 28

End point description:

End point type	Primary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease	Baseline CKD	Baseline non-CKD
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	10[17]	10[18]	11[19]	11
Units: RU / ml				
arithmetic mean (standard deviation)	452.94 (± 403.14)	82.29 (± 99.66)	805.6 (± 535.8)	302.5 (± 464.8)

Notes:

[17] - 2 missing data

[18] - 1 missing data

[19] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis cFGF23-CKD - Day 28
Comparison groups	Chronic Kidney Disease v Baseline CKD
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	generalized least squares linear model

Statistical analysis title	Analysis cFGF23-non-CKD - Day 28
Comparison groups	Non Chronic Kidney Disease v Baseline non-CKD
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	generalized least squares linear model

Secondary: Phosphate - Day 0 pre-infusion

End point title	Phosphate - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: mmol / l				
arithmetic mean (standard deviation)	1.223 (± 0.2526)	1.028 (± 0.1991)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate - Day 0 post-infusion

End point title	Phosphate - Day 0 post-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 post-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: mmol / l				
arithmetic mean (standard deviation)	1.247 (± 0.2582)	1.086 (± 0.2080)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate - Day 1

End point title	Phosphate - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: mmol / l				
arithmetic mean (standard deviation)	1.118 (± 0.3269)	1.056 (± 0.2063)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate - Day 7

End point title	Phosphate - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[20]	11		
Units: mmol / l				
arithmetic mean (standard deviation)	0.9690 (± 0.3981)	0.7609 (± 0.2021)		

Notes:

[20] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate - Day 14

End point title	Phosphate - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[21]	10[22]		
Units: mmol / l				
arithmetic mean (standard deviation)	1.080 (± 0.4695)	0.693 (± 0.2067)		

Notes:

[21] - 2 missing data

[22] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate - Day 28

End point title	Phosphate - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[23]	10[24]		
Units: mmol / l				
arithmetic mean (standard deviation)	1.063 (± 0.2968)	0.884 (± 0.1992)		

Notes:

[23] - 2 missing data

[24] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate excretion - Day 0 pre-infusion

End point title	Phosphate excretion - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	28.300 (± 14.365)	9.986 (± 5.642)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate excretion - Day 0 post-infusion

End point title	Phosphate excretion - Day 0 post-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 post-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	32.26 (± 15.826)	11.57 (± 7.705)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate excretion - Day 1

End point title	Phosphate excretion - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	39.40 (± 17.630)	18.03 (± 9.794)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate excretion - Day 7

End point title	Phosphate excretion - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	28.24 (± 19.00)	23.97 (± 12.27)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate excretion - Day 14

End point title	Phosphate excretion - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	31.67 (± 20.54)	21.25 (± 13.91)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phosphate excretion - Day 28

End point title	Phosphate excretion - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	24.97 (± 17.26)	17.63 (± 11.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: 1.25 OH Vit D - Day 0 pre-infusion

End point title	1.25 OH Vit D - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ng / l				
arithmetic mean (standard deviation)	30.90 (± 13.50)	40.45 (± 11.28)		

Statistical analyses

No statistical analyses for this end point

Secondary: 1.25 OH Vit D - Day 0 post-infusion

End point title	1.25 OH Vit D - Day 0 post-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 post-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ng / l				
arithmetic mean (standard deviation)	29.62 (± 14.63)	40.00 (± 10.64)		

Statistical analyses

No statistical analyses for this end point

Secondary: 1.25 OH Vit D - Day 1

End point title	1.25 OH Vit D - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ng / l				
arithmetic mean (standard deviation)	26.80 (± 15.938)	28.21 (± 8.363)		

Statistical analyses

No statistical analyses for this end point

Secondary: 1.25 OH Vit D - Day 7

End point title	1.25 OH Vit D - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[25]	10[26]		
Units: ng / l				
arithmetic mean (standard deviation)	16.18 (± 10.760)	13.33 (± 6.989)		

Notes:

[25] - 2 missing data

[26] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: 1.25 OH Vit D - Day 14

End point title	1.25 OH Vit D - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[27]	10[28]		
Units: ng / l				
arithmetic mean (standard deviation)	16.69 (± 10.36)	19.57 (± 12.07)		

Notes:

[27] - 3 missing data

[28] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: 1.25 OH Vit D - Day 28

End point title	1.25 OH Vit D - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[29]	8[30]		
Units: ng / l				
arithmetic mean (standard deviation)	27.94 (± 5.34)	34.2 (± 14.6)		

Notes:

[29] - 2 missing data

[30] - 3 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: NGAL - Day 0 pre-infusion

End point title	NGAL - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: nmol / ml				
arithmetic mean (standard deviation)	309295 (± 105612.1)	107982 (± 52683.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: NGAL - Day 1

End point title	NGAL - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: nmol / ml				
arithmetic mean (standard deviation)	283856 (± 79849.1)	144358 (± 73936.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: NGAL - Day 7

End point title	NGAL - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[31]	11		
Units: nmol / ml				
arithmetic mean (standard deviation)	263126 (± 112889.5)	112302 (± 63389.2)		

Notes:

[31] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: NGAL - Day 14

End point title	NGAL - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[32]	10[33]		
Units: nmol / ml				
arithmetic mean (standard deviation)	288120 (± 117247)	103499 (± 101550)		

Notes:

[32] - 3 missing data

[33] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: NGAL - Day 28

End point title	NGAL - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[34]	10[35]		
Units: nmol / ml				
arithmetic mean (standard deviation)	284504 (± 13690.3)	104953 (± 79767.5)		

Notes:

[34] - 2 missing data

[35] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: KIM-1 - Day 0 pre-infusion

End point title	KIM-1 - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: pg / ml				
arithmetic mean (standard deviation)	1347.875 (± 1137.276)	446.379 (± 645.098)		

Statistical analyses

No statistical analyses for this end point

Secondary: KIM-1 - Day 1

End point title	KIM-1 - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: pg / ml				
arithmetic mean (standard deviation)	983.667 (± 880.098)	427.091 (± 545.736)		

Statistical analyses

No statistical analyses for this end point

Secondary: KIM-1 - Day 7

End point title	KIM-1 - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[36]	11		
Units: pg / ml				
arithmetic mean (standard deviation)	1315.567 (± 1419.966)	511.712 (± 614.401)		

Notes:

[36] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: KIM-1 - Day 14

End point title	KIM-1 - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[37]	10[38]		
Units: pg / ml				
arithmetic mean (standard deviation)	1692.33 (± 1614.113)	530.75 (± 531.363)		

Notes:

[37] - 3 missing data

[38] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: KIM-1 - Day 28

End point title	KIM-1 - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[39]	10[40]		
Units: pg / ml				
arithmetic mean (standard deviation)	1275.433 (± 1119.956)	320.267 (± 401.454)		

Notes:

[39] - 2 missing data

[40] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 0 pre-infusion

End point title	IL-6 - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ng / l				
arithmetic mean (standard deviation)	15.2033 (± 10.3474)	16.8536 (± 15.3659)		

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 1

End point title	IL-6 - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ng / l				
arithmetic mean (standard deviation)	12.2008 (± 6.97318)	18.1291 (± 17.06064)		

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 7

End point title	IL-6 - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[41]	11		
Units: ng / l				
arithmetic mean (standard deviation)	12.5020 (± 11.6822)	18.2536 (± 30.2515)		

Notes:

[41] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 14

End point title	IL-6 - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[42]	10[43]		
Units: ng / l				
arithmetic mean (standard deviation)	12.922 (± 9.22766)	18.497 (± 37.18214)		

Notes:

[42] - 2 missing data

[43] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 28

End point title	IL-6 - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[44]	10[45]		
Units: ng / l				
arithmetic mean (standard deviation)	10.092 (± 5.35425)	13.441 (± 18.84567)		

Notes:

[44] - 2 missing data

[45] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: TNF-α - Day 0 pre-infusion

End point title	TNF-α - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ng / l				
arithmetic mean (standard deviation)	12.11667 (± 4.17064)	7.84545 (± 2.22412)		

Statistical analyses

No statistical analyses for this end point

Secondary: TNF-α - Day 1

End point title	TNF-α - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ng / l				
arithmetic mean (standard deviation)	13.28333 (± 4.97756)	9.14545 (± 2.68714)		

Statistical analyses

No statistical analyses for this end point

Secondary: TNF-α - Day 7

End point title	TNF-α - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[46]	11		
Units: ng / l				
arithmetic mean (standard deviation)	11.39 (± 2.51239)	7.90 (± 2.41039)		

Notes:

[46] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: TNF-α - Day 14

End point title	TNF-α - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[47]	10[48]		
Units: ng / l				
arithmetic mean (standard deviation)	12.37 (± 3.8836)	10.44 (± 12.1930)		

Notes:

[47] - 2 missing data

[48] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: TNF-α - Day 28

End point title	TNF-α - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[49]	10[50]		
Units: ng / l				
arithmetic mean (standard deviation)	12.91 (± 4.68483)	8.61 (± 3.62628)		

Notes:

[49] - 2 missing data

[50] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: hsCRP - Day 0 pre-infusion

End point title	hsCRP - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: mg / l				
arithmetic mean (standard deviation)	9.81 (± 10.67)	10.08 (± 15.67)		

Statistical analyses

No statistical analyses for this end point

Secondary: hsCRP - Day 1

End point title	hsCRP - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: mg / l				
arithmetic mean (standard deviation)	8.97 (± 10.87)	10.46 (± 16.98)		

Statistical analyses

No statistical analyses for this end point

Secondary: hsCRP - Day 7

End point title	hsCRP - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[51]	11		
Units: mg / l				
arithmetic mean (standard deviation)	11.26 (± 21.64)	16.25 (± 39.91)		

Notes:

[51] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: hsCRP - Day 14

End point title	hsCRP - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[52]	10[53]		
Units: mg / l				
arithmetic mean (standard deviation)	9.62 (± 15.12)	22.27 (± 63.63)		

Notes:

[52] - 2 missing data

[53] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: hsCRP - Day 28

End point title	hsCRP - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[54]	10[55]		
Units: mg / l				
arithmetic mean (standard deviation)	7.35 (± 7.32)	11.41 (± 28.08)		

Notes:

[54] - 2 missing data

[55] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: PTH - Day 0 pre-infusion

End point title	PTH - Day 0 pre-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: pg / ml				
arithmetic mean (standard deviation)	215.81 (± 207.38)	76.28 (± 54.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: PTH - Day 0 post-infusion

End point title	PTH - Day 0 post-infusion

End point description:

End point type	Secondary

End point timeframe:

Day 0 post-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11[56]	11		
Units: pg / ml				
arithmetic mean (standard deviation)	216.20 (± 189.82)	83.15 (± 71.55)		

Notes:

[56] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: PTH - Day 1

End point title	PTH - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: pg / ml				
arithmetic mean (standard deviation)	198.00 (± 300.89)	58.65 (± 34.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: PTH - Day 7

End point title	PTH - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[57]	11		
Units: pg / ml				
arithmetic mean (standard deviation)	208.28 (± 239.19)	81.45 (± 50.68)		

Notes:

[57] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: PTH - Day 14

End point title	PTH - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[58]	10[59]		
Units: pg / ml				
arithmetic mean (standard deviation)	234.23 (± 345.6)	73.49 (± 36.6)		

Notes:

[58] - 2 missing data

[59] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: PTH - Day 28

End point title	PTH - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[60]	10[61]		
Units: pg / ml				
arithmetic mean (standard deviation)	183.65 (± 213.31)	70.29 (± 32.55)		

Notes:

[60] - 2 missing data

[61] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Ferritin - Day 0 pre-infusion

End point title	Ferritin - Day 0 pre-infusion

End point description:

End point type	Other pre-specified

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[62]	10[63]		
Units: µg / l				
arithmetic mean (standard deviation)	45.1 (± 25.9)	82.9 (± 53.2)		

Notes:

[62] - 3 missing data

[63] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Ferritin - Day 0 post-infusion

End point title	Ferritin - Day 0 post-infusion

End point description:

End point type	Other pre-specified

End point timeframe:

Day 0 post-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[64]	10[65]		
Units: µg / l				
arithmetic mean (standard deviation)	45.9 (± 24.9)	74.5 (± 46.8)		

Notes:

[64] - 3 missing data

[65] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Ferritin - Day 1

End point title	Ferritin - Day 1

End point description:

End point type	Other pre-specified

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[66]	10[67]		
Units: µg / l				
arithmetic mean (standard deviation)	204.9 (± 127.7)	259.6 (± 55.2)		

Notes:

[66] - 3 missing data

[67] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Ferritin - Day 7

End point title	Ferritin - Day 7

End point description:

End point type	Other pre-specified

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8[68]	10[69]		
Units: µg / l				
arithmetic mean (standard deviation)	804.4 (± 309.9)	1032.0 (± 231.6)		

Notes:

[68] - 4 missing data

[69] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Ferritin - Day 14

End point title	Ferritin - Day 14

End point description:

End point type	Other pre-specified

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8[70]	8[71]		
Units: µg / l				
arithmetic mean (standard deviation)	554.1 (± 320.9)	719.1 (± 271.5)		

Notes:

[70] - 4 missing data

[71] - 3 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Ferritin - Day 28

End point title	Ferritin - Day 28

End point description:

End point type	Other pre-specified

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[72]	7[73]		
Units: µg / l				
arithmetic mean (standard deviation)	281.9 (± 153.1)	438.9 (± 176.0)		

Notes:

[72] - 5 missing data

[73] - 4 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: TSAT - Day 0 pre-infusion

End point title	TSAT - Day 0 pre-infusion

End point description:

End point type	Other pre-specified

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	13.00 (± 6.047)	18.78 (± 10.421)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: TSAT - Day 0 post-infusion

End point title	TSAT - Day 0 post-infusion

End point description:

End point type	Other pre-specified

End point timeframe:

Day 0 post-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	155.1 (± 56.11)	186.1 (± 41.74)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: TSAT - Day 1

End point title	TSAT - Day 1

End point description:

End point type	Other pre-specified

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage				
arithmetic mean (standard deviation)	109.3 (± 13.08)	115.8 (± 16.13)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: TSAT - Day 7

End point title	TSAT - Day 7

End point description:

End point type	Other pre-specified

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[74]	11		
Units: percentage				
arithmetic mean (standard deviation)	31.55 (± 10.08)	31.64 (± 11.63)		

Notes:

[74] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: TSAT - Day 14

End point title	TSAT - Day 14

End point description:

End point type	Other pre-specified

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[75]	10[76]		
Units: percentage				
arithmetic mean (standard deviation)	23.72 (± 6.208)	32.08 (± 8.901)		

Notes:

[75] - 2 missing data

[76] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: TSAT - Day 28

End point title	TSAT - Day 28

End point description:

End point type	Other pre-specified

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[77]	10[78]		
Units: percentage				
arithmetic mean (standard deviation)	22.36 (± 3.825)	31.17 (± 10.605)		

Notes:

[77] - 2 missing data

[78] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GFR - Day 0 pre-infusion

End point title	GFR - Day 0 pre-infusion

End point description:

End point type	Other pre-specified

End point timeframe:

Day 0 pre-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ml / min / m²				
arithmetic mean (standard deviation)	28.18 (± 9.062)	74.76 (± 15.998)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GFR - Day 0 post-infusion

End point title	GFR - Day 0 post-infusion

End point description:

End point type	Other pre-specified

End point timeframe:

Day 0 post-infusion

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ml / min / m²				
arithmetic mean (standard deviation)	28.11 (± 7.737)	76.25 (± 17.437)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GFR - Day 1

End point title	GFR - Day 1

End point description:

End point type	Other pre-specified

End point timeframe:

Day 1

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: ml / min / m²				
arithmetic mean (standard deviation)	29.93 (± 8.401)	74.41 (± 17.227)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GFR - Day 7

End point title	GFR - Day 7

End point description:

End point type	Other pre-specified

End point timeframe:

Day 7

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[79]	11		
Units: ml / min / m²				
arithmetic mean (standard deviation)	29.76 (± 9.912)	77.35 (± 23.388)		

Notes:

[79] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GFR - Day 14

End point title	GFR - Day 14

End point description:

End point type	Other pre-specified

End point timeframe:

Day 14

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[80]	10[81]		
Units: ml / min / m²				
arithmetic mean (standard deviation)	28.24 (± 8.737)	81.50 (± 20.077)		

Notes:

[80] - 2 missing data

[81] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GFR - Day 28

End point title	GFR - Day 28

End point description:

End point type	Other pre-specified

End point timeframe:

Day 28

End point values	Chronic Kidney Disease	Non Chronic Kidney Disease		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[82]	10[83]		
Units: ml / min / m²				
arithmetic mean (standard deviation)	32.29 (± 9.773)	80.60 (± 22.622)		

Notes:

[82] - 2 missing data

[83] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 4 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	none
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 0 %

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: No adverse events occurred in this short-term study (study duration of 4 weeks per patient). No new risks were identified and there was no increase in known risks. During the study no safety measures had to be taken for safety reasons.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 June 2017	additional visit after 24 hours

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32215701

http://www.ncbi.nlm.nih.gov/pubmed/29747838