Clinical trial results:
A clinical trial collecting Data from routine ophthalmological examinations of patients who were randomized to either finerenone or placebo in the two Bayer-sponsored Phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD to investigate the effect of Finerenone on delaying the progression of Diabetic Retinopathy

Summary

EudraCT number	2020-003865-20
Trial protocol	BG
Global end of trial date	30 June 2021

Results information

Result version number	v1 (current)
This version publication date	15 July 2022
First version publication date	15 July 2022
Summary attachment (see zip file)	21618_Study Synopsis (21618_Study Synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	BAY94-8862/21618

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04795726
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser-Wilhelm-Allee, Leverkusen, Germany, D-51368
Public contact	Therapeutic Area Head, Bayer AG, 49 30 300139003,
Scientific contact	Therapeutic Area Head, Bayer AG, 49 30 300139003,

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	12 July 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of orally administered finerenone on the progression of diabetic retinopathy compared to placebo

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and the International Council for Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent was read by and explained to all the subjects. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 March 2021
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	Bulgaria: 47
Country: Number of subjects enrolled	United Kingdom: 10
Worldwide total number of subjects	57
EEA total number of subjects	47

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)	38

From 65 to 84 years	19
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study was conducted at 11 centers in 2 countries, between 10-Mar-2021 (first subject first visit) and 27-May-2021 (last subject last visit).

Pre-assignment

Screening details:

A total of 74 subjects (38 finerenone, 36 placebo) were screened (signed informed consent) from the studies FIDELIO-DKD (29 subjects) and the FIGARO-DKD (45 subjects). 70 of them (36 finerenone, 34 placebo) had available ophthalmological assessments (including screening failures). 57 subjects (29 finerenone, 28 placebo) were included in the FAS.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Finerenone

Arm description:

Subjects received treatment in phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD

Arm type	Experimental
Investigational medicinal product name	Finerenone (Kerendia, BAY94-8862)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg or 20 mg Finerenone tablet was taken once daily, only administered in the FIDELIO-DKD or FIGARO-DKD clinical trial. Subject didn't take treatment in this study.

Arm title	Placebo

Arm description:

Subjects received placebo in phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Matching placebo was taken once daily, only administered in the FIDELIO-DKD or FIGARO-DKD clinical trial. Subject didn't take treatment in this study.

Number of subjects in period 1	Finerenone	Placebo
Started	29	28
Completed	26	25
Not completed	3	3
Physician decision	1	-
Consent withdrawn by subject	1	1
Adverse event, non-fatal	1	2

Baseline characteristics

Reporting groups	
Reporting group title	Finerenone
Reporting group description:	
Subjects received treatment in phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo in phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD	

Reporting group values	Finerenone	Placebo	Total
Number of subjects	29	28	57
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	19	19	38
From 65-84 years	10	9	19
85 years and over	0	0	0
Gender Categorical Units: Subjects			
Female	18	8	26
Male	11	20	31
Race Units: Subjects			
White	27	26	53
Black or African American	2	1	3
Asian	0	1	1
Ethnicity Units: Subjects			
Not Hispanic or Latino	29	28	57

End points

End points reporting groups

Reporting group title	Finerenone
Reporting group description:	
Subjects received treatment in phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo in phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD	
Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description:	
All participants enrolled and allocated to this study.	

Primary: Number of subjects with progression of non-proliferative diabetic retinopathy (NPDR) at End of Year 2

End point title	Number of subjects with progression of non-proliferative diabetic retinopathy (NPDR) at End of Year 2
End point description:	
Progression of non-proliferative diabetic retinopathy (NPDR) defined by the occurrence of vision-threatening events i.e. proliferative diabetic retinopathy (PDR), diabetic macular edema (DME), anterior segment neovascularization (ASN) until the end of Year 2 after start of treatment	
End point type	Primary
End point timeframe:	
After start of treatment until end of Year 2	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	28		
Units: Subjects	0	1		

Statistical analyses

Statistical analysis title	Treatment difference propotion
Statistical analysis description:	
95% confidence intervals (CIs) for the treatment difference based on a two-sided z-test for the difference of two proportions (Finerenone-placebo) using normal approximation.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.3085
Method	z-test
Parameter estimate	Treatment difference propotion
Point estimate	-0.036

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.104
upper limit	0.033

Secondary: Number of subjects with progression of non-proliferative diabetic retinopathy (NPDR) at End of Year 1

End point title	Number of subjects with progression of non-proliferative diabetic retinopathy (NPDR) at End of Year 1

End point description:

Progression of non-proliferative diabetic retinopathy (NPDR) defined by the occurrence of vision-threatening events i.e. proliferative diabetic retinopathy (PDR), diabetic macular edema (DME), anterior segment neovascularization (ASN) until the end of Year 1 after start of treatment

End point type	Secondary

End point timeframe:

After start of treatment until end of Year 1

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	28		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with progression of NPDR to Proliferative Diabetic Retinopathy (PDR)

End point title	Number of subjects with progression of NPDR to Proliferative Diabetic Retinopathy (PDR)

End point description:

End point type	Secondary

End point timeframe:

After start of treatment until end of Year 1, and until the end of Year 2

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	28		
Units: Subjects				
End of Year 1	0	0		
End of Year 2	0	1		

Statistical analyses

Statistical analysis title	Treatment difference propotion until Year 2

Statistical analysis description:

95% confidence intervals (CIs) for the treatment difference based on a two-sided z-test for the difference of two proportions (unpooled variances) using normal approximation

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.3085
Method	z-test
Parameter estimate	Treatment difference propotion
Point estimate	-0.036
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.104
upper limit	0.033

Secondary: Number of subjects with diabetic macular edema (DME)

End point title	Number of subjects with diabetic macular edema (DME)

End point description:

End point type	Secondary

End point timeframe:

After start of treatment until end of Year 1 and end of Year 2

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	28		
Units: Subjects				
End of Year 1	0	0		
End of Year 2	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anterior segment neovascularization (ASN)

End point title	Number of subjects with anterior segment neovascularization (ASN)

End point description:

End point type	Secondary

End point timeframe:

After start of treatment until end of Year 1 and end of Year 2

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	28		
Units: Subjects				
End of Year 1	0	0		
End of Year 2	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in severity of diabetic retinopathy (DR)

End point title	Change in severity of diabetic retinopathy (DR)

End point description:

Severity grades of DR are: No DR, NPDR (mild or moderate), NPDR (severe) and PDR

End point type	Secondary

End point timeframe:

From start of treatment to the end of Year 1 and end of Year 2

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[1]	28[2]		
Units: Subjects				
At End of Year 1- Progression	0	0		
At End of Year 1- Improvement	0	1		
At End of Year 1- No change	11	7		
At End of Year 1-Unknown	18	20		
At End of Year 2- Progression	0	1		
At End of Year 2- Improvement	0	0		
At End of Year 2- No change	5	6		
At End of Year 2-Unknown	24	21		

Notes:

[1] - 18 subjects missed assessment at End of Year 1, 24 subjects missed assessment at End of Year 2

[2] - 20 subjects missed assessment at End of Year 1, 21 subjects missed assessment at End of Year 2

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

After the first dose of study drug up to 3 days after any temporary or permanent interruption of study drug, with an average treatment duration of 36 months

Adverse event reporting additional description:

Adverse Events Information as reported for the selected subset of subjects from study 16244 (EudraCT no. 2015-000990-11) and study 17530 (EudraCT no. 2015-000950-39) are provided. This study was conducted to support data collection for observational ReFineDR study 21311. ReFineDR study results could be found on https://clinicaltrials.bayer.com/.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects received placebo in phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD

Reporting group title	Finerenone

Reporting group description:

Subjects received treatment in phase 3 clinical trials FIDELIO-DKD and FIGARO-DKD

Serious adverse events	Placebo	Finerenone	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 28 (21.43%)	6 / 29 (20.69%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Peripheral vascular disorder			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Insertion of ambulatory peritoneal catheter			

subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastritis haemorrhagic			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Gangrene			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetic ketoacidosis			

subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 28 (0.00%)	5 / 29 (17.24%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Finerenone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 28 (64.29%)	18 / 29 (62.07%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostatic adenoma			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Hypotension			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Vitrectomy			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Transurethral bladder resection			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Retinopexy			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Cataract operation			

subjects affected / exposed	1 / 28 (3.57%)	1 / 29 (3.45%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Oedema			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Pain			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 28 (3.57%)	1 / 29 (3.45%)	
occurrences (all)	1	1	
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 28 (3.57%)	1 / 29 (3.45%)	
occurrences (all)	1	1	
Blood creatinine increased			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Blood potassium increased			

subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Blood pressure increased			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
C-reactive protein increased			
subjects affected / exposed	1 / 28 (3.57%)	4 / 29 (13.79%)	
occurrences (all)	1	4	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 28 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Hand fracture			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Wrist fracture			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Vascular graft occlusion			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Contusion			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Cardiac disorders			
Mitral valve incompetence			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Ventricular extrasystoles			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Left ventricular hypertrophy			

subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Coronary artery stenosis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Bundle branch block right			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Neuralgic amyotrophy			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Anaemia			
subjects affected / exposed	2 / 28 (7.14%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 28 (3.57%)	2 / 29 (6.90%)	
occurrences (all)	2	2	
Eye disorders			
Retinal haemorrhage			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Retinopathy hypertensive			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Visual impairment			

subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Constipation			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Diarrhoea			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	2	
Haematochezia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Inguinal hernia			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Pancreatitis chronic			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Rash pruritic			

subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Pruritus			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Haematuria			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Renal cyst			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	2 / 28 (7.14%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Osteoarthritis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Myalgia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Ear infection			

subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Furuncle			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	3 / 28 (10.71%)	0 / 29 (0.00%)	
occurrences (all)	3	0	
Injection site infection			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Otitis externa			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Pneumonia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Viral infection			
subjects affected / exposed	2 / 28 (7.14%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Pyelonephritis chronic			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Respiratory tract infection viral			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Medical device site infection			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			

Obesity			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Hypomagnesaemia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Hypokalaemia			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Hypoglycaemia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Hyperuricaemia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Decreased appetite			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Hyperkalaemia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 28 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	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

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

In this study no additional safety data were collected. Adverse events information from study 16244 (EudraCT no. 2015-000990-11) and study 17530 (EudraCT no. 2015-000950-39) are provided.

Notes: