Clinical trial results:
A Phase 2, Double-blind, Active-controlled, Dose-titrating Efficacy and Safety Study of Firibastat (QGC001) Compared to Ramipril Administered Orally, Twice Daily, Over 12 Weeks to Prevent Left Ventricular Dysfunction after Acute Myocardial Infarction

Summary

EudraCT number	2018-003146-17
Trial protocol	DE SK HU ES GB
Global end of trial date	08 July 2021

Results information

Result version number	v1 (current)
This version publication date	18 December 2022
First version publication date	18 December 2022
Summary attachment (see zip file)	CSR Synopsis (CSR_QUORUM_VF_3Fev2022 - Synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	QGC001-2QG4

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03715998
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Quantum Genomics
Sponsor organisation address	33 rue Marbeuf, Paris, France,
Public contact	Clinical Project Manager, Quantum Genomics, mariette.codou@quantum-genomics.com
Scientific contact	Clinical Project Manager, Quantum Genomics, mariette.codou@quantum-genomics.com

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	27 July 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 July 2021
Global end of trial reached?	Yes
Global end of trial date	08 July 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Comparison of the effects of twice daily (bis in die [BID]) oral administration of 2 doses of firibastat to those of BID oral administration of ramipril on the change from Baseline in left ventricular ejection fraction (LVEF) assessed by cardiac magnetic resonance imaging (CMRI) on Day 84

Protection of trial subjects:

If symptomatic hypotension, symptomatic orthostatic hypotension, or cardiogenic shock occur, the treatment will be discontinued for the remainder of the study, and the event will be recorded as an AE leading to discontinuation.
In case a skin reaction is concomitant to fever, blisters on the skin, and/or the mucous membranes of the mouth, nose, eyes and genitals, peeling and shedding skin, which may suggest erythema multiforme or Stevens-Johnson syndrome, the treatment must be immediately discontinued.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 February 2019
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	Poland: 74
Country: Number of subjects enrolled	Slovakia: 70
Country: Number of subjects enrolled	Spain: 28
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	France: 40
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Hungary: 67
Worldwide total number of subjects	295
EEA total number of subjects	290

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)	206
From 65 to 84 years	84
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

A total of 295 male and female patients with a diagnosis of first acute anterior MI were randomized. The patients had a primary percutaneous coronary intervention (PCI) of the index-MI-related artery within 24 hours after MI. Patients were randomly assigned to 1 of the 3 treatment groups in a 1:1:1 ratio.

Pre-assignment

Screening details:

The population for this study corresponds to adults patients with a first acute anterior MI treated with primary PCI and signed an ICF.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

Patients were randomly assigned to 1 of the following 3 treatment groups in a 1:1:1 ratio:
• Group 1: Patients received 50 mg firibastat BID for 2 weeks and then 100 mg BID for 10 weeks.
• Group 2: Patients received 250 mg firibastat BID for 2 weeks and then 500 mg BID for 10 weeks.
• Group 3: Patients received 2.5 mg ramipril BID for 2 weeks and then 5 mg BID for 10 weeks.
IP was produced in order to maintain the blind (similar bottles with similar caps). IP allocation via IRT.

Arms

Are arms mutually exclusive?	Yes
Arm title	Firibastat 100 mg BID

Arm description:

50 mg firibastat BID for 2 weeks and then 100 mg BID for 10 weeks

Arm type	Experimental
Investigational medicinal product name	Firibastat
Investigational medicinal product code	QGC001
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Firibastat 100 mg BID (2 caps of 50mg twice a day)

Arm title	Firibastat 500mg BID

Arm description:

250 mg firibastat BID for 2 weeks and then 500 mg BID for 10 weeks

Arm type	Experimental
Investigational medicinal product name	Firibastat
Investigational medicinal product code	QGC001
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Firibastat 500 mg BID (2 caps of 250mg twice a day)

Arm title	Ramipril 5 mg BID

Arm description:

2.5 mg ramipril BID for 2 weeks and then 5 mg BID for 10 weeks.

Arm type	Active comparator
Investigational medicinal product name	Ramipril
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Rapmipril 2.5mg 2 caps twice a day

Number of subjects in period 1	Firibastat 100 mg BID	Firibastat 500mg BID	Ramipril 5 mg BID
Started	98	99	98
Completed	81	80	88
Not completed	17	19	10
Adverse event, serious fatal	2	1	1
Adverse event, non-fatal	5	10	5
Subject decision	9	6	2
Pregnancy	1	-	-
Lost to follow-up	-	1	1
Protocol deviation	-	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Firibastat 100 mg BID
Reporting group description:	
50 mg firibastat BID for 2 weeks and then 100 mg BID for 10 weeks	
Reporting group title	Firibastat 500mg BID
Reporting group description:	
250 mg firibastat BID for 2 weeks and then 500 mg BID for 10 weeks	
Reporting group title	Ramipril 5 mg BID
Reporting group description:	
2.5 mg ramipril BID for 2 weeks and then 5 mg BID for 10 weeks.	

Reporting group values	Firibastat 100 mg BID	Firibastat 500mg BID	Ramipril 5 mg BID
Number of subjects	98	99	98
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)	74	64	68
From 65-84 years	22	33	29
85 years and over	2	2	1
Gender categorical Units: Subjects			
Female	30	23	25
Male	68	76	73

Reporting group values	Total		
Number of subjects	295		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	206		
From 65-84 years	84		
85 years and over	5		

Gender categorical Units: Subjects			
Female	78		
Male	217		

End points

End points reporting groups

Reporting group title	Firibastat 100 mg BID
Reporting group description:	
50 mg firibastat BID for 2 weeks and then 100 mg BID for 10 weeks	
Reporting group title	Firibastat 500mg BID
Reporting group description:	
250 mg firibastat BID for 2 weeks and then 500 mg BID for 10 weeks	
Reporting group title	Ramipril 5 mg BID
Reporting group description:	
2.5 mg ramipril BID for 2 weeks and then 5 mg BID for 10 weeks.	
Subject analysis set title	mITT
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
The mITT population included 229 patients (77.6% of the randomized population) who received at least 1 dose of the IP and who had at least 1 baseline (before or within 8 hours of taking the first IP) and 1 post-baseline efficacy assessment (LVEF), with 72 (73.5%) patients in the firibastat 100 mg BID group, 77 (77.8%) patients in the firibastat 500 mg BID group and 80 (81.6%) patients in the ramipril group.	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
The ITT population included all randomized population (N=295) for each treatment groups, with 98 patients in the firibastat 100 mg BID group, 99 patients in the firibastat 500 mg BID group and 98 patients in the ramipril group	
Subject analysis set title	Safety
Subject analysis set type	Safety analysis
Subject analysis set description:	
The safety population included 294 patients (99.7% of the randomized population) who received at least one dose of the IP, with 98 (100%) patients in the firibastat 100 mg BID group, 98 (99.0%) patients in the firibastat 500 mg BID group and 98 (100%) patients in the ramipril group	
Subject analysis set title	PP
Subject analysis set type	Per protocol
Subject analysis set description:	
The PP population included 170 patients (57.6% of the randomized population) without major protocol deviations, with 56 (57.1%) patients in the firibastat 100 mg BID group, 48 (48.5%) patients in the firibastat 500 mg BID group and 66 (67.3%) patients in the ramipril group	

Primary: Change from Baseline to Day 84 in LVEF

End point title	Change from Baseline to Day 84 in LVEF
End point description:	
Change from Baseline to Day 84 in LVEF assessed by CMRI (central reading)	
End point type	Primary
End point timeframe:	
84 days	

End point values	Firibastat 100 mg BID	Firibastat 500mg BID	Ramipril 5 mg BID	mITT
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	72	77	80	229
Units: % of Left Ventricular Ejection Fraction				
arithmetic mean (standard deviation)	5.6 (± 1.2)	5.3 (± 1.1)	5.7 (± 1.1)	-0.36 (± 1.32)

Statistical analyses

Statistical analysis title	Primary analysis of the primary efficacy endpoint
Comparison groups	Firibastat 100 mg BID v Firibastat 500mg BID v Ramipril 5 mg BID
Number of subjects included in analysis	229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.789
Method	ANCOVA

Secondary: Left-ventricule End-Diastolic Volume

End point title	Left-ventricule End-Diastolic Volume
End point description:	
Change from Baseline to Day 84 in left-ventricular end-diastolic and end-systolic volumes assessed by CMRI (centralized reading).	
End point type	Secondary
End point timeframe:	
Day 84	

End point values	Firibastat 100 mg BID	Firibastat 500mg BID	Ramipril 5 mg BID	mITT
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	72	77	80	229
Units: mL				
arithmetic mean (standard deviation)	14.2 (± 4.5)	12.7 (± 4.3)	9.4 (± 4.4)	3.29 (± 5.13)

Statistical analyses

Statistical analysis title	Analysis of the Secondary Efficacy endpoint
Statistical analysis description:	
9.2.2.1 Change in left-ventricular end-diastolic and end-systolic volumes at EOT	
Comparison groups	Firibastat 100 mg BID v Firibastat 500mg BID v Ramipril 5 mg BID

Number of subjects included in analysis	229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.521
Method	ANCOVA

Secondary: Left-ventricule End-systolic Volume

End point title	Left-ventricule End-systolic Volume

End point description:

Change from Baseline to Day 84 in left-ventricular end-systolic volumes assessed by CMRI (centralized reading).

End point type	Secondary

End point timeframe:

Day 84

End point values	Firibastat 100 mg BID	Firibastat 500mg BID	Ramipril 5 mg BID	mITT
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	72	77	80	229
Units: mL				
arithmetic mean (standard deviation)	-0.5 (± 3.3)	-0.4 (± 3.2)	-3.1 (± 3.2)	2.75 (± 3.82)

Statistical analyses

Statistical analysis title	Analysis of the Secondary Efficacy endpoint
Comparison groups	Firibastat 100 mg BID v Firibastat 500mg BID v Ramipril 5 mg BID
Number of subjects included in analysis	229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.473
Method	ANCOVA

Secondary: MACE (i.e., cardiovascular deaths, new MIs, and cardiac hospitalizations)

End point title	MACE (i.e., cardiovascular deaths, new MIs, and cardiac hospitalizations)

End point description:

Major cardiac events as adjudicated by an independent committee by treatment group

End point type	Secondary

End point timeframe:

Day 84

End point values	Firibastat 100 mg BID	Firibastat 500mg BID	Ramipril 5 mg BID	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	98	98	98	294
Units: Event	10	8	6	24

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in NT-proBNP,

End point title	Change from Baseline in NT-proBNP,

End point description:

End point type	Secondary

End point timeframe:

Day 84

End point values	Firibastat 100 mg BID	Firibastat 500mg BID	Ramipril 5 mg BID	mITT
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	62	71	70	229
Units: pg/ml				
arithmetic mean (standard deviation)	-1360.0 (± 1381.7)	-1596.4 (± 2279.6)	-1735.6 (± 2326.5)	246.8 (± 127)

Statistical analyses

Statistical analysis title	Analysis of the Secondary Efficacy endpoint
Comparison groups	Firibastat 100 mg BID v Firibastat 500mg BID v Ramipril 5 mg BID
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.053
Method	ANCOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From ICF signature to end of treatment	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	24
Reporting groups	
Reporting group title	Firibastat 100mg
Reporting group description: -	
Reporting group title	Firibastat 500mg
Reporting group description: -	
Reporting group title	Ramipril 5 mg
Reporting group description: -	

Serious adverse events	Firibastat 100mg	Firibastat 500mg	Ramipril 5 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 98 (11.22%)	18 / 98 (18.37%)	10 / 98 (10.20%)
number of deaths (all causes)	2	1	1
number of deaths resulting from adverse events	2	1	1
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain or chest disconfort			
subjects affected / exposed	1 / 98 (1.02%)	1 / 98 (1.02%)	3 / 98 (3.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			

subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vascular stent thrombosis			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dry throat			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprocedural myocardial infarction			

subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	1 / 98 (1.02%)	2 / 98 (2.04%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac tamponade			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Coronary artery syndrome	Additional description: ae		
subjects affected / exposed	2 / 98 (2.04%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricule rupture			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 98 (1.02%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	2 / 98 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Skin and subcutaneous tissue disorders			
Drug eruption			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	2 / 98 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperplasia Adrenal			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Spinal pain			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 98 (1.02%)	3 / 98 (3.06%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary tract infection			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 98 (1.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Firibastat 100mg	Firibastat 500mg	Ramipril 5 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 98 (4.08%)	13 / 98 (13.27%)	19 / 98 (19.39%)
Cardiac disorders			
Chest disconfort			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	5 / 98 (5.10%)
occurrences (all)	0	0	5
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 98 (1.02%)	1 / 98 (1.02%)	5 / 98 (5.10%)
occurrences (all)	1	1	6
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 98 (0.00%)	8 / 98 (8.16%)	3 / 98 (3.06%)
occurrences (all)	0	9	3
Infections and infestations			
COVID-19			
subjects affected / exposed	3 / 98 (3.06%)	4 / 98 (4.08%)	6 / 98 (6.12%)
occurrences (all)	3	4	6

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