



Clinical trial results:

IOCYTE AMI-3: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Intravenous FDY-5301 in Patients with an Anterior ST-Elevation Myocardial Infarction

Summary

EudraCT number	2021-001924-16
Trial protocol	HU SK ES PL PT CZ NL IT
Global end of trial date	03 September 2025

Results information

Result version number	v1 (current)
This version publication date	15 January 2026
First version publication date	15 January 2026

Trial information

Trial identification

Sponsor protocol code	FDY-5301-302
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04837001
WHO universal trial number (UTN)	U1111-1308-0435

Notes:

Sponsors

Sponsor organisation name	Faraday Pharmaceuticals, Inc.
Sponsor organisation address	1616 Eastlake Ave E, Suite 560, Seattle, United States, 98102
Public contact	Stephen Hill, MD, CEO, Stephen Hill, MD, CEO, 1 (706) 621-6504, faradaypharma@gmail.com
Scientific contact	Stephen Hill, MD, CEO, Stephen Hill, MD, CEO, 1 (706) 621-6504, faradaypharma@gmail.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 October 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 September 2025
Global end of trial reached?	Yes
Global end of trial date	03 September 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effect of FDY-5301 on cardiovascular mortality and heart failure events in subjects with an anterior STEMI undergoing pPCI.

Protection of trial subjects:

This trial complied with the International Conference on Harmonization Tripartite Guideline on Good Clinical Practice, the ethical principles stated in the latest version of the Declaration of Helsinki, and the applicable local and international regulations, whichever provided the greater protection of the individual.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 May 2022
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	Netherlands: 226
Country: Number of subjects enrolled	Poland: 203
Country: Number of subjects enrolled	Portugal: 69
Country: Number of subjects enrolled	Slovakia: 98
Country: Number of subjects enrolled	Spain: 621
Country: Number of subjects enrolled	Czechia: 159
Country: Number of subjects enrolled	Germany: 25
Country: Number of subjects enrolled	Hungary: 247
Country: Number of subjects enrolled	Italy: 169
Country: Number of subjects enrolled	Canada: 38
Country: Number of subjects enrolled	United States: 37
Country: Number of subjects enrolled	Israel: 193
Country: Number of subjects enrolled	United Kingdom: 266
Worldwide total number of subjects	2351
EEA total number of subjects	1817

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)	1440
From 65 to 84 years	855
85 years and over	56

Subject disposition

Recruitment

Recruitment details:

The first participant enrolled on May 02, 2022. Study centers were located in 13 countries which were Canada, Czechia, Germany, Hungary, Israel, Italy, Netherlands, Poland, Portugal, Slovakia, Spain, United Kingdom, and United States. The study ended on Sept 03, 2025.

Pre-assignment

Screening details:

A total of 2,351 subjects were randomized 1:1 to receive either the study drug or placebo, of which 2,317 received study treatment. The Full Analysis Set (FAS) and safety population included intent-to-treat (ITT) subjects who received study treatment.

Pre-assignment period milestones

Number of subjects started	2351
Number of subjects completed	2317

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Physician decision: 19
Reason: Number of subjects	Other: 14
Reason: Number of subjects	Consent withdrawn by subject: 1

Period 1

Period 1 title	Administration of Study Treatment (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

Arms

Are arms mutually exclusive?	Yes
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Arm title	FDY-5301
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Arm description:

FDY-5301 (2mg/kg) was administered as a single IV bolus injection.

Arm type	Experimental
Investigational medicinal product name	FDY-5301
Investigational medicinal product code	20377
Other name	Sodium Iodide
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Following an anterior STEMI diagnosis, based on clinical and electrocardiogram (ECG) findings and the receipt of informed consent, randomized subjects were dosed with a single bolus intravenous administration of FDY-5301 \leq 6 hours of myocardial ischemia symptom onset. The full dose of investigational product was administered at any time between 60 minutes and 5 minutes prior to pPCI.

Arm title	Placebo
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Arm description:

Placebo (normal saline) was administered as a single IV bolus injection.

Arm type	Placebo
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Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Following an anterior STEMI diagnosis, based on clinical and electrocardiogram (ECG) findings and the receipt of informed consent, randomized subjects were dosed with a single bolus intravenous administration of volume matched placebo \leq 6 hours of myocardial ischemia symptom onset. The full dose of investigational product was administered at any time between 60 minutes and 5 minutes prior to pPCI.

Number of subjects in period 1^[1]	FDY-5301	Placebo
Started	1164	1153
Completed	1088	1077
Not completed	76	76
Adverse event, serious fatal	60	51
Consent withdrawn by subject	9	14
Lost to follow-up	7	11

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The ITT population includes all randomized subjects (2,351). The Full Analysis Set (FAS) population (2,317) includes all intent-to-treat (ITT) subjects who received investigational product.

Baseline characteristics

Reporting groups

Reporting group title	FDY-5301
Reporting group description: FDY-5301 (2mg/kg) was administered as a single IV bolus injection.	
Reporting group title	Placebo
Reporting group description: Placebo (normal saline) was administered as a single IV bolus injection.	

Reporting group values	FDY-5301	Placebo	Total
Number of subjects	1164	1153	2317
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)	717	709	1426
From 65-84 years	411	424	835
85 years and over	36	20	56
Gender categorical Units: Subjects			
Female	183	176	359
Male	981	977	1958
Race Units: Subjects			
Asian	30	32	62
Native Hawaiian or Other Pacific Islander	1	0	1
Black or African American	10	14	24
White	1091	1071	2162
More than one race	2	2	4
Unknown or Not Reported	30	34	64
Ethnicity Units: Subjects			
Hispanic or Latino	72	76	148
Not Hispanic or Latino	1051	1029	2080
Unknown or Not Reported	41	48	89
Weight			
The FAS included subjects who received study treatment and totaled 2,317 subjects.			
Units: kg			
arithmetic mean	82.78	83.00	
standard deviation	± 15.74	± 15.56	-
Height			
This subject set included 1,159 subjects in the FDY-5301 arm and 1,147 subjects in the Placebo arm.			

There are 11 subjects with a missing height in the database (5 FDY-5301 and 6 placebo).			
Units: cm			
arithmetic mean	172.8	172.9	
standard deviation	± 8.64	± 8.50	-
Body Mass Index			
This subject set included 1,159 subjects in the FDY-5301 arm and 1,147 subjects in the Placebo arm. There are 11 subjects with a missing height in the database (5 FDY-5301 and 6 placebo).			
Units: kg/m2			
arithmetic mean	27.65	27.72	
standard deviation	± 4.50	± 4.55	-

Subject analysis sets

Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description:	
Includes all randomized subjects who received study treatment.	
Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis
Subject analysis set description:	
Includes all randomized subjects who received study treatment. Subjects were analyzed by the actual study treatment received.	

Reporting group values	Full Analysis Set	Safety Analysis Set	
Number of subjects	2317	2317	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	1426	1426	
From 65-84 years	835	835	
85 years and over	56	56	
Gender categorical			
Units: Subjects			
Female	359	359	
Male	1958	1958	
Race			
Units: Subjects			
Asian	62	62	
Native Hawaiian or Other Pacific Islander	1	1	
Black or African American	24	24	
White	2162	2162	
More than one race	4	4	
Unknown or Not Reported	64	64	
Ethnicity			
Units: Subjects			

Hispanic or Latino	148	148	
Not Hispanic or Latino	2080	2080	
Unknown or Not Reported	89	89	
Weight			
The FAS included subjects who received study treatment and totaled 2,317 subjects.			
Units: kg			
arithmetic mean	82.89	82.89	
standard deviation	± 15.65	± 15.65	
Height			
This subject set included 1,159 subjects in the FDY-5301 arm and 1,147 subjects in the Placebo arm. There are 11 subjects with a missing height in the database (5 FDY-5301 and 6 placebo).			
Units: cm			
arithmetic mean	172.8	172.8	
standard deviation	± 8.57	± 8.57	
Body Mass Index			
This subject set included 1,159 subjects in the FDY-5301 arm and 1,147 subjects in the Placebo arm. There are 11 subjects with a missing height in the database (5 FDY-5301 and 6 placebo).			
Units: kg/m2			
arithmetic mean	27.68	27.68	
standard deviation	± 4.52	± 4.52	

End points

End points reporting groups

Reporting group title	FDY-5301
Reporting group description: FDY-5301 (2mg/kg) was administered as a single IV bolus injection.	
Reporting group title	Placebo
Reporting group description: Placebo (normal saline) was administered as a single IV bolus injection.	
Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description: Includes all randomized subjects who received study treatment.	
Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis
Subject analysis set description: Includes all randomized subjects who received study treatment. Subjects were analyzed by the actual study treatment received.	

Primary: Cardiovascular Mortality or Heart Failure

End point title	Cardiovascular Mortality or Heart Failure
End point description: The proportion of subjects who experience either cardiovascular mortality or a heart failure event.	
End point type	Primary
End point timeframe: Through Month 12	

End point values	FDY-5301	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	1164 ^[1]	1153 ^[2]	2317 ^[3]	
Units: Number of events	1164	1153	2317	

Notes:

[1] - Excludes subjects who did not receive study treatment.

[2] - Excludes subjects who did not receive study treatment.

[3] - All subjects who received study treatment.

Statistical analyses

Statistical analysis title	Analysis of the Primary Efficacy Endpoint
Statistical analysis description: The proportion of the events were estimated using the Kaplan-Meier Method.	
Comparison groups	FDY-5301 v Placebo

Number of subjects included in analysis	2317
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3589 ^[4]
Method	z-test
Parameter estimate	Risk difference (RD)
Point estimate	-0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.38
upper limit	2.33
Variability estimate	Standard error of the mean
Dispersion value	1.458

Notes:

[4] - one-sided

Secondary: All-cause Mortality or Heart Failure

End point title	All-cause Mortality or Heart Failure
End point description:	
The proportion of subjects who experience either all-cause mortality or a heart failure event.	
End point type	Secondary
End point timeframe:	
Through Month 12	

End point values	FDY-5301	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	1164 ^[5]	1153 ^[6]	2317 ^[7]	
Units: Number of events	1164	1153	2317	

Notes:

[5] - Excluded subjects who did not receive study treatment.

[6] - Excluded subjects who did not receive study treatment.

[7] - All subjects who received study treatment.

Statistical analyses

Statistical analysis title	Analysis of First Secondary Endpoint
Comparison groups	FDY-5301 v Placebo
Number of subjects included in analysis	2317
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2983 ^[8]
Method	z-test
Parameter estimate	Risk difference (RD)
Point estimate	-0.79

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.71
upper limit	2.13
Variability estimate	Standard error of the mean
Dispersion value	1.491

Notes:

[8] - one-sided

Secondary: Cardiovascular Events

End point title	Cardiovascular Events
End point description:	
The total number of cardiovascular events defined as cardiovascular mortality and heart failure events.	
End point type	Secondary
End point timeframe:	
Through Month 12	

End point values	FDY-5301	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	1164 ^[9]	1153 ^[10]	2317 ^[11]	
Units: Number of events	1164	1153	2317	

Notes:

[9] - All subjects who received study treatment.

[10] - All subjects who received study treatment.

[11] - All subjects who received study treatment.

Statistical analyses

Statistical analysis title	Analysis of Second Secondary Endpoint
Comparison groups	FDY-5301 v Placebo
Number of subjects included in analysis	2317
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4226 ^[12]
Method	Regression, Cox
Parameter estimate	Mean difference (net)
Point estimate	-0.004
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.044
upper limit	0.036
Variability estimate	Standard error of the mean
Dispersion value	0.02

Notes:

[12] - one-sided

Secondary: Other Non-Fatal Cardiovascular Morbidity

End point title	Other Non-Fatal Cardiovascular Morbidity
End point description: The proportion of subjects who experience a composite of the following specified non-fatal cardiovascular events: thromboembolic cerebral vascular accident (CVA), ventricular aneurysm/hemorrhage, recurrent myocardial infarction (e.g., remote or stent thrombosis), or persistent arrhythmia requiring intervention (e.g., ventricular fibrillation, sustained ventricular tachycardia, or bradyarrhythmia).	
End point type	Secondary
End point timeframe: Through Month 12	

End point values	FDY-5301	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	1164 ^[13]	1153 ^[14]	2317 ^[15]	
Units: Number of events	1164	1153	2317	

Notes:

[13] - All subjects who received study treatment.

[14] - All subjects who received study treatment.

[15] - All subjects who received study treatment.

Statistical analyses

Statistical analysis title	Analysis of Third Secondary Endpoint
Comparison groups	FDY-5301 v Placebo
Number of subjects included in analysis	2317
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2953 ^[16]
Method	z-test
Parameter estimate	Risk difference (RD)
Point estimate	-0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.46
upper limit	1.97
Variability estimate	Standard error of the mean
Dispersion value	1.385

Notes:

[16] - one-sided

Secondary: Serum Troponin T

End point title	Serum Troponin T
End point description: Serum high-sensitivity troponin T levels from approximately 500 subjects were collected at sponsor designated sites and countries only.	

For the Subject analysis set 1, the percent relative difference in the geometric least-square means.

End point type	Secondary
End point timeframe:	
Day 3	

End point values	FDY-5301	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	235 ^[17]	276 ^[18]	511 ^[19]	
Units: ug/L				
geometric mean (standard error)	1.936 (± 0.401)	1.880 (± 0.393)	2.949 (± 11.284)	

Notes:

[17] - Subjects who received study treatment and had Troponin T measured on Day 3.

[18] - Subjects who received study treatment and had Troponin T measured on Day 3.

[19] - Subjects who received study treatment and had Troponin T measured on Day 3.

Statistical analyses

Statistical analysis title	Analysis of Fourth Secondary Endpoint
Comparison groups	FDY-5301 v Placebo
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3945 ^[20]
Method	ANCOVA
Parameter estimate	Ratio of Geometric Means
Point estimate	1.029
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.3
Variability estimate	Standard error of the mean
Dispersion value	1.115

Notes:

[20] - one-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From study treatment until Day 28

Adverse event reporting additional description:

The 'non-serious adverse events' section includes both serious and non-serious events. Prespecified cardiovascular endpoints (refer to protocol) were excluded from AE reporting, recorded only on endpoint CRFs, and not reported as AEs within 24 hours. After adjudication, events not meeting endpoint criteria were reported as AEs/SAEs through Day 28.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	FDY-5301
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Reporting group description:

FDY-5301 was administered as a single IV bolus injection.

During the first 28 days after receiving the study treatment, 6 subjects died who got the study drug and these early deaths are reported as adverse events, separate from the topline results on subjects who either experienced heart failure or dying from heart-related causes (cardiovascular mortality).

Reporting group title	Placebo
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Reporting group description:

During the first 28 days after receiving the study treatment, 9 subjects died and these early deaths are reported here as adverse events, separate from the topline results on subjects who either experienced heart failure or dying from heart-related causes (cardiovascular mortality).

Serious adverse events	FDY-5301	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	92 / 1164 (7.90%)	116 / 1153 (10.06%)	
number of deaths (all causes)	6	9	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac neoplasm unspecified			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Hypotension			
subjects affected / exposed	7 / 1164 (0.60%)	5 / 1153 (0.43%)	
occurrences causally related to treatment / all	1 / 7	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	1 / 1164 (0.09%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Aortic stenosis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic thrombosis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			

subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial vein thrombosis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 1164 (0.09%)	3 / 1153 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	1 / 1164 (0.09%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Non-cardiac chest pain			
subjects affected / exposed	1 / 1164 (0.09%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site haemorrhage			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyrexia			

subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Immune system disorders			
Contrast media reaction			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 1164 (0.00%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 1164 (0.00%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 1164 (0.00%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hydrothorax			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Delirium			
subjects affected / exposed	3 / 1164 (0.26%)	4 / 1153 (0.35%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Ejection fraction decreased			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Cardiac procedure complication			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural hypotension			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site pseudoaneurysm			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular procedure complication			

subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac ventricular thrombosis			
subjects affected / exposed	6 / 1164 (0.52%)	12 / 1153 (1.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	3 / 1164 (0.26%)	9 / 1153 (0.78%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Angina pectoris			
subjects affected / exposed	5 / 1164 (0.43%)	3 / 1153 (0.26%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	4 / 1164 (0.34%)	4 / 1153 (0.35%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systolic dysfunction			
subjects affected / exposed	4 / 1164 (0.34%)	3 / 1153 (0.26%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	5 / 1164 (0.43%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			
subjects affected / exposed	1 / 1164 (0.09%)	3 / 1153 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery perforation			

subjects affected / exposed	1 / 1164 (0.09%)	3 / 1153 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary no-reflow phenomenon			
subjects affected / exposed	1 / 1164 (0.09%)	3 / 1153 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dressler's syndrome			
subjects affected / exposed	2 / 1164 (0.17%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	2 / 1164 (0.17%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 1164 (0.09%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	1 / 1164 (0.09%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	1 / 1164 (0.09%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery dissection			
subjects affected / exposed	0 / 1164 (0.00%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery embolism			

subjects affected / exposed	0 / 1164 (0.00%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriospasm coronary			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery thrombosis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary slow flow phenomenon			

subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal rhythm			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prinzmetal angina			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 1164 (0.00%)	3 / 1153 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			

subjects affected / exposed	1 / 1164 (0.09%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Middle cerebral artery stroke			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			

subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar stroke			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Blood loss anaemia			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 1164 (0.09%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 1164 (0.09%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Melaena			
subjects affected / exposed	0 / 1164 (0.00%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Colitis ischaemic			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			

subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	2 / 1164 (0.17%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 1164 (0.17%)	5 / 1153 (0.43%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal failure			
subjects affected / exposed	2 / 1164 (0.17%)	4 / 1153 (0.35%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haematuria			
subjects affected / exposed	0 / 1164 (0.00%)	2 / 1153 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal haemorrhage			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	11 / 1164 (0.95%) 0 / 11 0 / 0	8 / 1153 (0.69%) 0 / 8 0 / 0	
COVID-19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 1164 (0.17%) 0 / 2 0 / 0	2 / 1153 (0.17%) 0 / 2 0 / 0	
Sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 1164 (0.09%) 0 / 1 0 / 0	3 / 1153 (0.26%) 0 / 3 0 / 1	
Lower respiratory tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1164 (0.00%) 0 / 0 0 / 0	3 / 1153 (0.26%) 0 / 3 0 / 0	
Respiratory tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 1164 (0.09%) 0 / 7 0 / 0	2 / 1153 (0.17%) 0 / 2 0 / 0	
Septic shock subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 1164 (0.26%) 0 / 3 0 / 1	0 / 1153 (0.00%) 0 / 0 0 / 0	
Clostridium difficile infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 1164 (0.09%) 0 / 1 0 / 0	1 / 1153 (0.09%) 0 / 1 0 / 0	
Staphylococcal bacteraemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 1164 (0.09%) 0 / 1 0 / 0	1 / 1153 (0.09%) 0 / 1 0 / 0	
Urinary tract infection			

subjects affected / exposed	1 / 1164 (0.09%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			

subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 1164 (0.09%)	0 / 1153 (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			
Hyponatraemia			
subjects affected / exposed	0 / 1164 (0.00%)	1 / 1153 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	FDY-5301	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	657 / 1164 (56.44%)	620 / 1153 (53.77%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	44 / 1164 (3.78%)	47 / 1153 (4.08%)	
occurrences (all)	46	51	
Hypertension			
subjects affected / exposed	31 / 1164 (2.66%)	23 / 1153 (1.99%)	
occurrences (all)	41	26	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	16 / 1164 (1.37%)	27 / 1153 (2.34%)	
occurrences (all)	18	28	
Non-cardiac chest pain			
subjects affected / exposed	19 / 1164 (1.63%)	19 / 1153 (1.65%)	
occurrences (all)	20	19	
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	13 / 1164 (1.12%) 13	17 / 1153 (1.47%) 17	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	5 / 1164 (0.43%) 5	13 / 1153 (1.13%) 13	
Investigations Ejection fraction decreased subjects affected / exposed occurrences (all) Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	27 / 1164 (2.32%) 27 10 / 1164 (0.86%) 11	22 / 1153 (1.91%) 22 12 / 1153 (1.04%) 13	
Cardiac disorders Cardiac ventricular thrombosis subjects affected / exposed occurrences (all) Ventricular tachycardia subjects affected / exposed occurrences (all) Cardiac failure subjects affected / exposed occurrences (all) Pericarditis subjects affected / exposed occurrences (all) Angina pectoris subjects affected / exposed occurrences (all) Coronary artery embolism subjects affected / exposed occurrences (all) Left ventricular dysfunction subjects affected / exposed occurrences (all)	41 / 1164 (3.52%) 41 49 / 1164 (4.21%) 53 31 / 1164 (2.66%) 33 36 / 1164 (3.09%) 36 23 / 1164 (1.98%) 28 21 / 1164 (1.80%) 26 24 / 1164 (2.06%) 25	48 / 1153 (4.16%) 48 37 / 1153 (3.21%) 37 32 / 1153 (2.78%) 33 27 / 1153 (2.34%) 27 26 / 1153 (2.25%) 27 26 / 1153 (2.25%) 27 23 / 1153 (1.99%) 23	

<p>Atrial fibrillation</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Coronary artery dissection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Coronary no-reflow phenomenon</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pericardial effusion</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Bradycardia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Coronary slow flow phenomenon</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	17 / 1164 (1.46%)	21 / 1153 (1.82%)	
	18	21	
	15 / 1164 (1.29%)	21 / 1153 (1.82%)	
	19	23	
	15 / 1164 (1.29%)	17 / 1153 (1.47%)	
	17	17	
	13 / 1164 (1.12%)	15 / 1153 (1.30%)	
	13	15	
	5 / 1164 (0.43%)	11 / 1153 (0.95%)	
	5	12	
	15 / 1164 (1.29%)	8 / 1153 (0.69%)	
	16	8	
Nervous system disorders			
	Dizziness		
	subjects affected / exposed	15 / 1164 (1.29%)	12 / 1153 (1.04%)
	occurrences (all)	15	13
	Headache		
	subjects affected / exposed	12 / 1164 (1.03%)	11 / 1153 (0.95%)
	occurrences (all)	12	11
Blood and lymphatic system disorders			
	Anaemia		
	subjects affected / exposed	16 / 1164 (1.37%)	16 / 1153 (1.39%)
	occurrences (all)	19	17
Gastrointestinal disorders			
	Nausea		
	subjects affected / exposed	34 / 1164 (2.92%)	20 / 1153 (1.73%)
	occurrences (all)	35	24
	Vomiting		
	subjects affected / exposed	21 / 1164 (1.80%)	18 / 1153 (1.56%)
	occurrences (all)	21	21
	Diarrhoea		

subjects affected / exposed occurrences (all)	22 / 1164 (1.89%) 22	8 / 1153 (0.69%) 9	
Constipation subjects affected / exposed occurrences (all)	13 / 1164 (1.12%) 13	11 / 1153 (0.95%) 11	
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	17 / 1164 (1.46%) 19	19 / 1153 (1.65%) 20	
Haematuria subjects affected / exposed occurrences (all)	8 / 1164 (0.69%) 8	13 / 1153 (1.13%) 13	
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	11 / 1164 (0.95%) 11	15 / 1153 (1.30%) 15	
Infections and infestations Pneumonia subjects affected / exposed occurrences (all)	23 / 1164 (1.98%) 23	16 / 1153 (1.39%) 16	
Urinary tract infection subjects affected / exposed occurrences (all)	15 / 1164 (1.29%) 15	13 / 1153 (1.13%) 13	
COVID-19 subjects affected / exposed occurrences (all)	16 / 1164 (1.37%) 16	7 / 1153 (0.61%) 7	
Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all)	34 / 1164 (2.92%) 47	20 / 1153 (1.73%) 27	
Hypercholesterolaemia subjects affected / exposed occurrences (all)	15 / 1164 (1.29%) 17	17 / 1153 (1.47%) 20	
Diabetes mellitus subjects affected / exposed occurrences (all)	10 / 1164 (0.86%) 10	15 / 1153 (1.30%) 17	

Hyperlipidaemia			
subjects affected / exposed	12 / 1164 (1.03%)	9 / 1153 (0.78%)	
occurrences (all)	23	13	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 October 2023	<p>The modifications to the protocol were as follows:</p> <ul style="list-style-type: none">• Modification of the interim analysis to allow the inclusion of subjects that have completed at least 28 days of the 12-month follow-up for the primary endpoint.• Corresponding modifications to the statistical analysis methodology by utilizing the Kaplan-Meier method for both interim and final analysis.• Clarification of the heart failure definition and to allow for the use of clinical judgement in the setting of insufficient documentation.• Clarification of inclusion and exclusion criteria.• Broadening of inpatient study visit windows to accommodate physician workflow.• General clarification statements and incorporation of updates due to requests from global regulatory agencies and ethic committees.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported