Clinical trial results:
Prevention of Mortality with Long-Term Administration of Human Albumin in Subjects with Decompensated Cirrhosis and Ascites

Summary

EudraCT number	2016-001789-28
Trial protocol	ES DE FR BE GB DK IT HU BG PL
Global end of trial date	21 May 2024

Results information

Result version number	v1 (current)
This version publication date	06 June 2025
First version publication date	06 June 2025

Trial information

Trial identification

Sponsor protocol code	IG1601

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03451292
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Instituto Grifols, S.A.
Sponsor organisation address	Can Guasch, Parets del Vallès, Barcelona, Spain, 08150
Public contact	Clinical and Pharmacovigilance, Instituto Grifols S.A., +34 935712200, IGregulatory.affairs@grifols.com
Scientific contact	Clinical and Pharmacovigilance, Instituto Grifols S.A., +34 935712200, IGregulatory.affairs@grifols.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	21 May 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 May 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of the study is to evaluate the effect of standard medical treatment (SMT) plus long-term Albutein 20% (SMT + Albutein 20%) administration on 1-year transplant-free survival versus SMT alone. The study population will consist of participants being discharged after hospitalization for acute decompensation of liver cirrhosis with ascites (or with prior history of ascites requiring diuretic therapy) with or without acute-on-chronic liver failure (ACLF) at admission or during hospitalization but without ACLF at discharge.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 July 2018
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: 43
Country: Number of subjects enrolled	Spain: 29
Country: Number of subjects enrolled	United Kingdom: 9
Country: Number of subjects enrolled	Belgium: 16
Country: Number of subjects enrolled	Bulgaria: 84
Country: Number of subjects enrolled	Denmark: 1
Country: Number of subjects enrolled	France: 19
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Hungary: 20
Country: Number of subjects enrolled	Italy: 47
Country: Number of subjects enrolled	United States: 69
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	Bosnia and Herzegovina: 9
Country: Number of subjects enrolled	Serbia: 49
Worldwide total number of subjects	410
EEA total number of subjects	271

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)	279
From 65 to 84 years	131
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 410 participants took part in the study at 40 investigative sites across 14 countries in Europe and the United States from 24 July 2018 to 21 May 2024.

Pre-assignment

Screening details:

476 participants with decompensated cirrhosis and ascites were screened of which 410 participants were randomized in a 1:1 ratio to receive either the SMT + Albutein 20% or the SMT alone.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	SMT + Albutein 20%

Arm description:

Participants received Albutein 20%, at a dose of 1.5 grams/kilograms (g/kg), based on their body weight (maximum 100 grams per participant), as an intravenous (IV) infusion on Day 1, followed by the same dose of Albutein 20% every 10±2 days along with SMT administered as per institution standards for the management of decompensated cirrhosis up to 12 months.

Arm type	Experimental
Investigational medicinal product name	Albutein 20%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1.5 g/kg based on body weight (maximum 100 grams per participant) on Day 1 and every 10±2 days thereafter up to 12 months.

Investigational medicinal product name	Standard Medical Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:

SMT administered as per institution standards for the management of decompensated cirrhosis up to 12 months.

Arm title	SMT Alone

Arm description:

Participants received SMT up to 12 months as per institution standards for the management of decompensated cirrhosis.

Arm type	Active comparator
Investigational medicinal product name	Standard Medical Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:

SMT administered as per institution standards for the management of decompensated cirrhosis up to 12 months.

Number of subjects in period 1	SMT + Albutein 20%	SMT Alone
Started	203	207
Completed	110	105
Not completed	93	102
Consent withdrawn by subject	18	13
Physician decision	4	3
Non-compliance with Study Drug	2	-
Adverse event, non-fatal	3	3
Death	44	59
Lost to follow-up	4	12
Transplantation	18	12

Baseline characteristics

Reporting groups	
Reporting group title	SMT + Albutein 20%
Reporting group description:	
Participants received Albutein 20%, at a dose of 1.5 grams/kilograms (g/kg), based on their body weight (maximum 100 grams per participant), as an intravenous (IV) infusion on Day 1, followed by the same dose of Albutein 20% every 10±2 days along with SMT administered as per institution standards for the management of decompensated cirrhosis up to 12 months.	
Reporting group title	SMT Alone
Reporting group description:	
Participants received SMT up to 12 months as per institution standards for the management of decompensated cirrhosis.	

Reporting group values	SMT + Albutein 20%	SMT Alone	Total
Number of subjects	203	207	410
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	58.9	58.7	
standard deviation	± 10.03	± 10.30	-
Gender categorical Units: Subjects			
Female	62	55	117
Male	141	152	293
Ethnicity Units: Subjects			
Hispanic or Latino	18	17	35
Not Hispanic or Latino	185	190	375
Unknown or Not Reported	0	0	0
Race Units: Subjects			
White	197	199	396
Black or African American	2	4	6
Asian	3	1	4
American Indian or Alaskan Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
More than one race	0	1	1
Unknown or Not Reported	1	2	3

End points

End points reporting groups

Reporting group title	SMT + Albutein 20%

Reporting group description:

Participants received Albutein 20%, at a dose of 1.5 grams/kilograms (g/kg), based on their body weight (maximum 100 grams per participant), as an intravenous (IV) infusion on Day 1, followed by the same dose of Albutein 20% every 10±2 days along with SMT administered as per institution standards for the management of decompensated cirrhosis up to 12 months.

Reporting group title	SMT Alone

Reporting group description:

Participants received SMT up to 12 months as per institution standards for the management of decompensated cirrhosis.

Primary: Time to Liver Transplantation or Death Through 1 Year After Randomization: Percentage of Participants With an Event

End point title	Time to Liver Transplantation or Death Through 1 Year After Randomization: Percentage of Participants With an Event

End point description:

Time to one-year transplant-free survival was calculated as earlier of [(date of liver transplantation or date of death) – randomization date + 1] for participants who died or had liver transplant within the analysis period of 361 days. Participants who neither died nor had liver transplant within analysis period had their time to event censored at earlier of date of last contact or cut-off date. Participants who terminated early for reasons other than death were followed up at months 3, 6, and 12 to collect information on liver transplantation and death, these events if reported by cut-off Day 361, were considered for the endpoint. The percentage of participants with events are presented. The percentage of participants was calculated as [(participants with an event up to the analysis cut-off Day 361) / (number of participants in the ITT group)]. ITT population included all participants who were randomized.

End point type	Primary

End point timeframe:

Up to Day 361

End point values	SMT + Albutein 20%	SMT Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	207		
Units: percentage of participants				
number (not applicable)	33.5	38.6		

Statistical analyses

Statistical analysis title	SMT + Albutein 20% vs SMT Alone

Statistical analysis description:

Stratification factors included were the region (Europe or North America) and history of hospitalization for acute decompensation of liver cirrhosis (yes or no).

Comparison groups	SMT + Albutein 20% v SMT Alone

Number of subjects included in analysis	410
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.17
Method	Cox Proportional- Hazards (PH) model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.1

Secondary: Time to Liver Transplantation or Death Through 3 Months After Randomization: Percentage of Participants With an Event

End point title	Time to Liver Transplantation or Death Through 3 Months After Randomization: Percentage of Participants With an Event

End point description:

Time to 3-months transplant-free survival was calculated as earlier of [(date of liver transplantation or date of death) – randomization date + 1] for participants who died or had liver transplant within the analysis period of 91 days. Participants who neither died nor had liver transplant within analysis period had their time to event censored at earlier of date of last contact or cut-off date. Participants who terminated early for reasons other than death were followed up at months 3, 6, and 12 to collect information on liver transplantation and death, these events if reported by cut-off Day 91, were considered for the endpoint. The percentage of participants with events are presented. The percentage of participants was calculated as [(participants with an event up to the analysis cut-off Day 91) / (number of participants in the ITT group)]. ITT population included all participants who were randomized.

End point type	Secondary

End point timeframe:

Up to Day 91

End point values	SMT + Albutein 20%	SMT Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	207		
Units: percentage of participants				
number (not applicable)	10.8	17.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Liver Transplantation or Death Through 6 Months After Randomization: Percentage of Participants With an Event

End point title	Time to Liver Transplantation or Death Through 6 Months After Randomization: Percentage of Participants With an Event

End point description:

Time to 6-months transplant-free survival was calculated as earlier of [(date of liver transplantation or date of death) – randomization date + 1] for participants who died or had liver transplant within the analysis period of 181 days. Participants who neither died nor had liver transplant within analysis period had their time to event censored at earlier of date of last contact or cut-off date. Participants who terminated early for reasons other than death were followed up at months 3, 6, and 12 to collect information on liver transplantation and death, these events if reported by cut-off Day 181, were considered for the endpoint. The percentage of participants with events are presented. The percentage of participants was calculated as [(participants with an event up to the analysis cut-off Day 181) / (number of participants in the ITT group)]. ITT population included all participants who were randomized.

End point type	Secondary

End point timeframe:

Up to Day 181

End point values	SMT + Albutein 20%	SMT Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	207		
Units: percentage of participants				
number (not applicable)	22.7	28.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Death Through 3 Months After Randomization: Percentage of Participants With an Event

End point title	Time to Death Through 3 Months After Randomization: Percentage of Participants With an Event

End point description:

Time to 3-months survival was calculated as the earlier of [(date of death) - randomization date + 1] for those participants who died within the analysis period of 91 days. Participants who did not die within the analysis period were censored at the earlier of the date of last contact or analysis cut-off date. Participants who terminated early for reasons other than death were followed up at months 3, 6, and 12 to collect information on death, these events if reported before the analysis cut-off Day 91 of this endpoint, were considered. The percentage of participants with events (death) without censoring participants who underwent liver transplantation within the analysis period were reported. The percentage of participants was calculated as [(participants with an event up to the analysis cut-off Day 91) / (number of participants in the ITT group)]. ITT population included all participants who were randomized.

End point type	Secondary

End point timeframe:

Up to Day 91

End point values	SMT + Albutein 20%	SMT Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	207		
Units: percentage of participants				
number (not applicable)	9.4	14.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Death Through 6 Months After Randomization: Percentage of Participants With an Event

End point title	Time to Death Through 6 Months After Randomization: Percentage of Participants With an Event

End point description:

Time to 6-months survival was calculated as the earlier of [(date of death) - randomization date + 1] for those participants who died within the analysis period of 181 days. Participants who did not die within the analysis period were censored at the earlier of the date of last contact or analysis cut-off date. Participants who terminated early for reasons other than death were followed up at months 3, 6, and 12 to collect information on death, these events if reported before the analysis cut-off Day 181 of this endpoint, were considered. The percentage of participants with events (death) without censoring participants who underwent liver transplantation within the analysis period were reported. The percentage of participants was calculated as [(participants with an event up to the analysis cut-off Day 181) / (number of participants in the ITT group)]. ITT population included all participants who were randomized.

End point type	Secondary

End point timeframe:

Up to Day 181

End point values	SMT + Albutein 20%	SMT Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	207		
Units: percentage of participants				
number (not applicable)	16.7	23.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Death Through 1 Year After Randomization: Percentage of Participants With an Event

End point title	Time to Death Through 1 Year After Randomization: Percentage of Participants With an Event

End point description:

Time to 1 year survival was calculated as the earlier of [(date of death) - randomization date + 1] for those participants who died within the analysis period of 361 days. Participants who did not die within

the analysis period were censored at the earlier of the date of last contact or analysis cut-off date. Participants who terminated early for reasons other than death were followed up at months 3, 6, and 12 to collect information on death, these events if reported before the analysis cut-off Day 361 of this endpoint, were considered. The percentage of participants with events (death) without censoring participants who underwent liver transplantation within the analysis period were reported. The percentage of participants was calculated as [(participants with an event up to the analysis cut-off Day 361) / (number of participants in the ITT group)]. ITT population included all participants who were randomized.

End point type	Secondary

End point timeframe:

Up to Day 361

End point values	SMT + Albutein 20%	SMT Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	207		
Units: percentage of participants				
number (not applicable)	26.1	31.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Total Number of Paracenteses Through 1 Year After Randomization

End point title	Total Number of Paracenteses Through 1 Year After Randomization

End point description:

Paracenteses is a medical procedure used to remove excess fluid from the abdominal cavity. For each participant, the total number of reported paracenteses on treatment was calculated. Number of paracenteses per participant while on treatment was reported. ITT population included all participants who were randomized.

End point type	Secondary

End point timeframe:

Up to Day 361

End point values	SMT + Albutein 20%	SMT Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	207		
Units: paracenteses per participant				
arithmetic mean (standard deviation)	1.3 (± 3.58)	2.3 (± 5.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Refractory Ascites According to the International Club of Ascites (ICA) Through 1 Year After Randomization

End point title	Number of Participants With Refractory Ascites According to the International Club of Ascites (ICA) Through 1 Year After Randomization

End point description:

Refractory Ascites was defined as ascites that cannot be mobilized, or the early recurrence of which cannot be prevented because of a lack of response to sodium restriction and diuretic, or the development of diuretic-induced complications that preclude the use of an effective diuretic dosage treatment. Incidence of refractory ascites occurring on treatment was defined as any incidence that occurred with a start date/time on or after the participants date/time of randomization (for SMT Alone group) or commencement of Albutein (SMT+ Albutein 20% group) treatment. ITT population included all participants who were randomized. Number of participants analyzed included participants with at least one refractory ascites assessment.

End point type	Secondary

End point timeframe:

Up to Day 361

End point values	SMT + Albutein 20%	SMT Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	195	203		
Units: participants	33	46		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 12 months

Adverse event reporting additional description:

The Safety population included the subset of participants who received at least one SMT + Albutein 20% administration or SMT alone.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	SMT + Albutein 20%

Reporting group description:

Participants received Albutein 20%, at a dose of 1.5 g/kg, based on their body weight (maximum 100 grams per participant), as an IV infusion on Day 1, followed by the same dose of Albutein 20% every 10±2 days along with SMT administered as per institution standards for the management of decompensated cirrhosis up to 12 months.

Reporting group title	SMT Alone

Reporting group description:

Participants received SMT up to 12 months as per institution standards for the management of decompensated cirrhosis.

Serious adverse events	SMT + Albutein 20%	SMT Alone	
Total subjects affected by serious adverse events			
subjects affected / exposed	52 / 203 (25.62%)	70 / 207 (33.82%)	
number of deaths (all causes)	53	67	
number of deaths resulting from adverse events	22	28	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenoma			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			

subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular disorders			
Haematoma			
subjects affected / exposed	2 / 203 (0.99%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
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 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
General disorders and administration site conditions			
Death			
subjects affected / exposed	5 / 203 (2.46%)	4 / 207 (1.93%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 5	0 / 4	
Sudden death			
subjects affected / exposed	2 / 203 (0.99%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Pyrexia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

General physical health deterioration			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hernia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
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 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oedema peripheral			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
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			
Respiratory failure			
subjects affected / exposed	1 / 203 (0.49%)	5 / 207 (2.42%)	
occurrences causally related to treatment / all	1 / 1	0 / 5	
deaths causally related to treatment / all	1 / 1	0 / 3	
Acute respiratory failure			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary oedema			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (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 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Delirium tremens			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Device breakage			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Gram stain positive			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
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			
Subdural haematoma			
subjects affected / exposed	2 / 203 (0.99%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Clavicle fracture			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated incisional hernia			

subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone fissure			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Wrist fracture			

subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	2 / 203 (0.99%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac arrest			
subjects affected / exposed	2 / 203 (0.99%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cardiac failure acute			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiopulmonary failure			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiomyopathy			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial injury			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			

subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial fibrillation			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Epilepsy			
subjects affected / exposed	1 / 203 (0.49%)	3 / 207 (1.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			

subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
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			
Anaemia			
subjects affected / exposed	2 / 203 (0.99%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	2 / 203 (0.99%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal disorders			
Haematemesis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Constipation			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Small intestinal perforation			

subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 203 (0.00%)	4 / 207 (1.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 203 (0.00%)	2 / 207 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Duodenal perforation			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric perforation			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal obstruction			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
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	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia, obstructive			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (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	1 / 203 (0.49%)	3 / 207 (1.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			

subjects affected / exposed	0 / 203 (0.00%)	2 / 207 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 203 (0.99%)	8 / 207 (3.86%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 1	
Urinary tract infection			
subjects affected / exposed	2 / 203 (0.99%)	7 / 207 (3.38%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sepsis			
subjects affected / exposed	2 / 203 (0.99%)	5 / 207 (2.42%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 2	
COVID-19 pneumonia			
subjects affected / exposed	2 / 203 (0.99%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Septic shock			
subjects affected / exposed	1 / 203 (0.49%)	4 / 207 (1.93%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
COVID-19			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			

subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic candida			
subjects affected / exposed	1 / 203 (0.49%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal bacteraemia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 203 (0.00%)	3 / 207 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute endocarditis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal sepsis			

subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
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	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastroenteritis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia escherichia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Staphylococcal osteomyelitis			

subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Lactic acidosis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 203 (0.99%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 207 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			

subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 207 (0.48%)	
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: 5 %

Non-serious adverse events	SMT + Albutein 20%	SMT Alone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	51 / 203 (25.12%)	47 / 207 (22.71%)	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	14 / 203 (6.90%)	17 / 207 (8.21%)	
occurrences (all)	15	21	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	11 / 203 (5.42%)	8 / 207 (3.86%)	
occurrences (all)	12	9	
Skin and subcutaneous tissue disorders			

Pruritus subjects affected / exposed occurrences (all)	12 / 203 (5.91%) 14	2 / 207 (0.97%) 2	
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)	13 / 203 (6.40%) 16	15 / 207 (7.25%) 16	
Metabolism and nutrition disorders Hyperkalaemia subjects affected / exposed occurrences (all)	11 / 203 (5.42%) 12	8 / 207 (3.86%) 9	
Hypokalaemia subjects affected / exposed occurrences (all)	7 / 203 (3.45%) 9	11 / 207 (5.31%) 16	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 July 2018	Included the description to clarify the exact test for albumin functional capacity.
19 December 2018	Revised screening window to facilitate participant enrollment.
11 March 2020	• Revised the related objectives and endpoints to allow the possibility to capture other disease-related complications. • Revised criteria to include screening of participants who are hospitalized regardless of whether they were discharged or not. Randomization timeframe also clarified which was within 72 hours of screening. • Randomization timeframe also clarified which occurred within 72 hours of screening instead of 120 hours (5 days) of screening and within 28 days of hospital discharge. • Defined dual anti-platelet therapy or anti-coagulation prior to enrollment within 7 days rather than 30 days as previously defined. • Updates to inclusion and exclusion criteria • Removed hospital discharge timeframe prior to randomization. • Clarified the duration of treatment. • Revised to make screening occurred during hospitalization and randomization to occur within 72 hours of screening. • Further clarified that randomization occurred within 72 hours of screening and first dose of Albutein was administered on the same day as randomization. • Defined dual anti-platelet therapy or anti-coagulation prior to enrolment within 7 days rather than 30 days as previously defined • Included hyponatremia to the list of anticipated disease progression.
24 September 2020	New exclusion criteria added regarding infection of COVID-19.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported