Clinical trial results:
Efficacy and safety of Octagam 10% therapy in COVID-19 patients with severe disease progression

Summary

EudraCT number	2020-002482-34
Trial protocol	Outside EU/EEA
Global end of trial date	31 January 2022

Results information

Result version number	v1 (current)
This version publication date	31 January 2024
First version publication date	31 January 2024

Trial information

Trial identification

Sponsor protocol code	GAM10-10

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04400058
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Octapharma Pharmazeutika Produktionsges.m.b.H
Sponsor organisation address	Oberlaaerstr. 235, Vienna, Austria, 1100
Public contact	Clinical Research & Development, Octapharma Pharmazeutika Produktionsges.m.b.H, +43 (1) 610 320, ClinicalRDVienna@groups.octapharma.com
Scientific contact	Clinical Research & Development, Octapharma Pharmazeutika Produktionsges.m.b.H, +43 (1) 610 320, ClinicalRDVienna@groups.octapharma.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	31 January 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 February 2021
Global end of trial reached?	Yes
Global end of trial date	31 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

GAM10-10 was a randomized, double-blind, placebo-controlled, multicenter, 2-arm adaptive Phase 3 study, designed to evaluate the efficacy and safety of high-dose Octagam 10% therapy in subjects with severe COVID-19. The primary endpoint was stabilization or improvement in modality needed to maintain oxygen supplementation as measured by modality required to maintain oxygen at entry.

Protection of trial subjects:

The Protocol and amendments, a sample of the subject information and informed consent form and any other materials provided to the subjects for the study, and further requested information, were reviewed and approved by the Independent Ethics Committee (IEC)/Institutional Review Board (IRB) prior to the initiation of the study. The study was approved by the IEC/IRB and the Regulatory Authority before any investigational medicinal product (IMP) was shipped to the study sites and any subject was exposed to a study-related procedure.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 June 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Scientific research
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 126
Country: Number of subjects enrolled	Ukraine: 43
Country: Number of subjects enrolled	Russian Federation: 38
Worldwide total number of subjects	207
EEA total number of subjects	0

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	150
From 65 to 84 years	56
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

A total of 207 patients were enrolled between June 2020 and February 2021 at 23 sites across the United States, Ukraine and Russia

Pre-assignment

Screening details:

A total of 219 patients were screened, with 207 enrolled and randomized into Octagam 10% and placebo arm in 1:1 ratio

Period 1

Period 1 title	Core Study (33 Days)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Octagam 10%

Arm description:

Octagam 10%, 2 g/kg divided by 4 days (0.5 g/kg/day), administered by intravenous infusion over approximately 2 hours per day over 4 consecutive days

Arm type	Experimental
Investigational medicinal product name	Octagam 10%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Infusion

Dosage and administration details:

Octagam 10%, 2 g/kg divided by 4 days (0.5 g/kg/day), administered by intravenous infusion over approximately 2 hours per day over 4 consecutive days

Arm title	Saline Solution

Arm description:

IV saline solution placebo group

Arm type	Placebo
Investigational medicinal product name	Saline Solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Infusion

Dosage and administration details:

Saline Solution administered by intravenous infusion over approximately 2 hours per day over 4 consecutive days

Number of subjects in period 1	Octagam 10%	Saline Solution
Started	105	102
Completed	84	86
Not completed	21	16
Consent withdrawn by subject	2	1
Physician decision	1	-
Death unrelated to IP	12	6
Adverse event, non-fatal	-	2
Other	-	1
Lost to follow-up	6	6

Period 2	
Period 2 title	1 Year Follow-Up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded
Arms	
Are arms mutually exclusive?	No
Arm title	Octagam 10%
Arm description: Treated with Octagam 10%, in Period 1, no IMP treatment in Period 2	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Saline Solution
Arm description: Treated with IV saline solution placebo group in Period 1, no IMP treatment in Period 2	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	Octagam 10%	Saline Solution
Started	84	84
Completed	66	67
Not completed	18	17
Consent withdrawn by subject	2	1
Subject deceased	4	2
Lost to follow-up	12	14

Baseline characteristics

Reporting groups	
Reporting group title	Core Study (33 Days)

Reporting group description: -

Reporting group values	Core Study (33 Days)	Total	
Number of subjects	207	207	
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)	150	150	
From 65-84 years	56	56	
85 years and over	1	1	
Age continuous Units: years			
median	59		
full range (min-max)	26 to 89	-	
Gender categorical Units: Subjects			
Female	88	88	
Male	119	119	
BMI			
Subjects mean Body Mass Index (BMI)			
Units: Body Mass Index			
median	31.88		
standard deviation	± 5.934	-	

End points

End points reporting groups

Reporting group title	Octagam 10%
Reporting group description:	
Octagam 10%, 2 g/kg divided by 4 days (0.5 g/kg/day), administered by intravenous infusion over approximately 2 hours per day over 4 consecutive days	
Reporting group title	Saline Solution
Reporting group description:	
IV saline solution placebo group	
Reporting group title	Octagam 10%
Reporting group description:	
Treated with Octagam 10%, in Period 1, no IMP treatment in Period 2	
Reporting group title	Saline Solution
Reporting group description:	
Treated with IV saline solution placebo group in Period 1, no IMP treatment in Period 2	

Primary: Proportion of Subjects Reaching Stabilization or Improvement in Clinical Status at Day 7

End point title	Proportion of Subjects Reaching Stabilization or Improvement in Clinical Status at Day 7
End point description:	
Proportion of subjects reaching stabilization or improvement in clinical status at Day 7 on at least one category on a 6-point clinical status scale. Clinical status categories were be defined as: 1. Hospital discharge or meet discharge criteria (discharge criteria were defined as clinical recovery, i.e. no fever, respiratory rate, oxygen saturation return to normal, and cough relief). 2. Hospitalization, not requiring supplemental oxygen. 3. Hospitalization, requiring supplemental oxygen (but not NIV/HFNC). 4. ICU/hospitalization, requiring NIV/HFNC therapy, as defined by A-a Gradient ≥150mmHg. 5. ICU, requiring Extracorporeal Membrane Oxygenation (ECMO) and/or IMV. 6. Death.	
End point type	Primary
End point timeframe:	
7 days	

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	102		
Units: Participants				
number (not applicable)				
Participants	89	82		
(%)	84.8	80.4		

Statistical analyses

Statistical analysis title	Subjects with stable or improved clinical status

Statistical analysis description:

Proportion of subjects with stable or improved clinical status at Day 7 in Octagam group compared to the placebo group. Clinical status category was based on a 6-point scale. Baseline clinical status was defined as the most recent value prior to treatment.

Comparison groups	Octagam 10% v Saline Solution
Number of subjects included in analysis	207
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.386
Method	Cochran-Mantel-Haenszel

Notes:

[1] - The null hypothesis of no difference in proportion of subjects who reach success in two treatment groups was tested vs. the alternative hypothesis that there that there is a difference between proportions of subjects who reach success in two groups. Hypothesis testing will be performed using Cochran-Mantel-Haenszel (CMH) stratified by age category (≤65 versus >65) at a two-sided 0.05 significance level.

Secondary: Length of Hospital Stay (Time to Discharge)

End point title	Length of Hospital Stay (Time to Discharge)

End point description:

Median length of hospital stay in subjects treated with Octagam 10% compared to those that received placebo from randomization through Day 33. Clinical status categories were defined as: Hospital discharge or meet discharge criteria (discharge criteria were defined as clinical recovery, i.e., no fever, respiratory rate, oxygensaturation return to normal, and cough relief.

End point type	Secondary

End point timeframe:

33 days

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	102		
Units: Days				
median (confidence interval 95%)				
Days	12 (9 to 14)	11 (9 to 15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reaching Stabilization or Improvement In Clinical Status at Day 14

End point title	Number of Subjects Reaching Stabilization or Improvement In Clinical Status at Day 14

End point description:

Number of subjects with maintenance or improvement by at least one category on the 6-point clinical status scale on Day 14.
Clinical status categories will be defined as:
1. Hospital discharge or meet discharge criteria (discharge criteria are defined as clinical recovery, i.e. no fever, respiratory rate, oxygen saturation return to normal, and cough relief).

2. Hospitalization, not requiring supplemental oxygen.
3. Hospitalization, requiring supplemental oxygen (but not NIV/HFNC).
4. ICU/hospitalization, requiring NIV/HFNC therapy,as defined by A-a Gradient ≥ 150 mmHg.
5. ICU, requiring Extracorporeal Membrane Oxygenation (ECMO) and/or IMV.
6. Death.

End point type	Secondary
End point timeframe: 14 days	

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	102		
Units: Participants				
Participants	86	83		

Statistical analyses

No statistical analyses for this end point

Secondary: Cumulative Duration of Invasive Mechanical Venitlation (IMV)

End point title	Cumulative Duration of Invasive Mechanical Venitlation (IMV)
End point description: Duration of invasive mechanical ventilation in subjects treated with Octagam 10% compared to placebo from randomization through Day 33	
End point type	Secondary
End point timeframe: 33 days	

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	102		
Units: Days				
arithmetic mean (standard deviation)				
Days	2.7 (± 8.05)	1.6 (± 5.95)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Severe Disease Progression

End point title	Number of Subjects With Severe Disease Progression

End point description:

Number of subjects who experienced severe disease progression while treated with Octagam 10% compared to those that received placebo at Day 33. Severe disease progression is defined as subjects requiring extracorporeal membrane oxygenation, mechanical ventilation and/or died through day 33.

End point type	Secondary

End point timeframe:

33 days

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	102		
Units: Participants				
Participants	15	12		

Statistical analyses

No statistical analyses for this end point

Secondary: ICU Stay Length

End point title	ICU Stay Length

End point description:

Average length of ICU stay in subjects treated with Octagam 10% compared to those that received placebo from randomization through Day 33.

End point type	Secondary

End point timeframe:

33 days

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	102		
Units: Days				
arithmetic mean (standard deviation)				
Days	4.6 (± 10.08)	3.9 (± 8.83)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cumulative Mortality Rate Through Day 33

End point title	Cumulative Mortality Rate Through Day 33

End point description:

Cumulative mortality in subjects treated with Octagam 10% compared to those that received placebo at Day 33

End point type	Secondary

End point timeframe:

33 days

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	102		
Units: Participants				
Participants	12	6		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Post Study Health Status, Any Residual Health Effects from COVID-19 or the Study Treatment - 3 Months Post-Study (COVID-19 Subject Questionnaire)

End point title	Post Study Health Status, Any Residual Health Effects from COVID-19 or the Study Treatment - 3 Months Post-Study (COVID-19 Subject Questionnaire)

End point description:

Subjects who completed the core study and entered the registry were administered questionnaires at 3 months asking about their general health. Subjects were asked:

How is your general health?
1. Poor
2. Fair
3. Good
4. Very Good
5. Excellent
6. Missing

How would you compare your general health now to what it was before you were ill with Covid-19?
1. Much worse
2. Somewhat worse
3. The same
4. Somewhat better
5. Much better
6. Missing

Since last contact, have you?
1. Been hospitalized
2. Sought consultation from a health care professional
3. Experienced deterioration of your health without seeking HCP consultation
4. None of the above
5. Missing

If the above question was not "none of the above", was it in relation to the symptoms?
1. Other
2. Similar to the symptoms experienced during COVID-19 hospitalization

Prior to Covid-19 did you work or go to school full time?
1. Yes
2. No

Do you currently work or go to school full time?
1. Yes
2. No

End point type	Post-hoc
End point timeframe:	
3 months post-study	

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	84		
Units: Number on a scale				
Question 1 - Poor	1	1		
Question 1 - Fair	14	24		
Question 1 - Good	30	30		
Question 1 - Very Good	19	15		
Question 1 - Excellent	6	5		
Question 1 - Missing Answer	14	9		
Question 2 - Much worse	3	5		
Question 2 - Somewhat Worse	18	29		
Question 2 - The Same	29	29		
Question 2 - Somewhat Better	11	7		
Question 2 - Much Better	9	5		
Question 2 - Missing Answer	14	9		
Question 3 - Been Hospitalized	2	7		
Question 3 - Sought Consultation from HCP	21	25		
Question 3 - Experienced deterioration of your hea	4	8		
Question 3 - None of the above	43	38		
Question 3 - Missing answer	14	9		
Question 4 - Other	23	27		
Question 4 - Similar to those during the COVID-19	9	13		
Question 5 - Yes	53	49		
Question 5 - No	17	26		
Question 6 - Yes	45	42		
Question 6 - No	25	32		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Post Study Health Status, Any Residual Health Effects From COVID-19 or the Study Treatment-6 Months Post-Study (COVID-19 Subject Questionnaire)

End point title	Post Study Health Status, Any Residual Health Effects From COVID-19 or the Study Treatment-6 Months Post-Study (COVID-19 Subject Questionnaire)

End point description:

Subjects who completed the core study and entered the registry were administered questionnaires at 6 months asking about their general health. Subjects were asked:

How is your general health?
1.Poor
2.Fair
3.Good
4.Very Good
5.Excellent
6.Missing

How would you compare your general health now to what it was before you were ill with Covid-19?
1.Much worse
2.Somewhat worse
3.The same
4.Somewhat better
5.Much better
6.Missing

Since last contact, have you?
1.Been hospitalized
2.Sought consultation from a health care professional
3.Experienced deterioration of your health without seeking HCP consultation
4.None of the above
5.Missing

If the above question was not "none of the above", was it in relation to the symptoms?
1.Other
2.Similar to the symptoms experienced during COVID-19 hospitalization
Prior to Covid-19 did you work or go to school full time?
1.Yes
2.No

Do you currently work or go to school full time?
1.Yes
2.No

End point type	Post-hoc

End point timeframe:

6 months post-study

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	84		
Units: participants				
number (not applicable)				
Question 1 - Poor	0	0		
Question 1 - Fair	15	20		
Question 1 - Good	26	22		
Question 1 - Very Good	18	19		
Question 1 - Excellent	4	7		
Question 1 - Missing Answer	21	16		
Question 2 - Much Worse	3	4		
Question 2 - Somewhat Worse	12	12		
Question 2 - The Same	30	38		
Question 2 - Somewhat Better	8	9		
Question 2 - Much Better	10	5		
Question 2 - Missing Answer	21	16		

Question 3 - Been Hospitalized	0	3		
Question 3 - Sought consultation from HCP	12	16		
Question 3 - Experienced deterioration of health	1	0		
Question 3 - None of the above	49	49		
Question 3 - Missing answer	22	16		
Question 4 - Other	6	18		
Question 4 -Similar to those during COVID-19 hosp.	6	4		
Question 5 - Yes	49	43		
Question 5 - No	13	25		
Question 6 - Yes	41	39		
Question 6 - No	21	29		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Post Study Health Status, Any Residual Health Effects From COVID-19 or the Study Treatment-9 Months Post-Study (COVID-19 Subject Questionnaire)

End point title	Post Study Health Status, Any Residual Health Effects From COVID-19 or the Study Treatment-9 Months Post-Study (COVID-19 Subject Questionnaire)

End point description:

Subjects who completed the core study and entered the registry were administered questionnaires at 9 months asking about their general health. Subjects were asked:

How is your general health?
1. Poor
2. Fair
3. Good
4. Very Good
5. Excellent
6. Missing

How would you compare your general health now to what it was before you were ill with Covid-19?
1. Much worse
2. Somewhat worse
3. The same
4. Somewhat better
5. Much better
6. Missing

Since last contact, have you?
1. Been hospitalized
2. Sought consultation from a health care professional
3. Experienced deterioration of your health without seeking HCP consultation
4. None of the above
5. Missing

If the above question was not "none of the above", was it in relation to the symptoms?
1. Other
2. Similar to the symptoms experienced during COVID-19 hospitalization

Prior to Covid-19 did you work or go to school full time?
1. Yes
2. No

Do you currently work or go to school full time?

1. Yes
2. No

End point type	Post-hoc
End point timeframe:	
9 months post-study	

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	84		
Units: participants				
number (not applicable)				
Question 1 - Poor	1	1		
Question 1 - Fair	10	19		
Question 1 - Good	29	31		
Question 1 - Very Good	19	14		
Question 1 - Excellent	4	4		
Question 1 - Missing Answer	21	15		
Question 2 - Much Worse	3	4		
Question 2 - Somewhat Worse	13	15		
Question 2 - The Same	28	38		
Question 2 - Somewhat Better	10	6		
Question 2 - Much Better	9	6		
Question 2 - Missing Answer	21	15		
Question 3 - Been Hospitalized	0	2		
Question 3 - Sought consultation from HCP	17	24		
Question 3 - Experienced deterioration of health	5	1		
Question 3 - None of the above	41	43		
Question 3 - Missing answer	21	15		
Question 4 - Other	15	23		
Question 4 -Similar to those during COVID-19 hosp.	9	4		
Question 5 - Yes	49	44		
Question 5 - No	14	25		
Question 6 - Yes	46	44		
Question 6 - No	17	25		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Post Study Health Status, Any Residual Health Effects From COVID-19 or the Study Treatment-12 Months Post-Study (COVID-19 Subject Questionnaire)

End point title	Post Study Health Status, Any Residual Health Effects From COVID-19 or the Study Treatment-12 Months Post-Study (COVID-19 Subject Questionnaire)

End point description:

Subjects who completed the core study and entered the registry were administered questionnaires at 12 months asking about their general health. Subjects were asked:

How is your general health?
1. Poor
2. Fair
3. Good
4. Very Good
5. Excellent
6. Missing

How would you compare your general health now to what it was before you were ill with Covid-19?
1. Much worse
2. Somewhat worse
3. The same
4. Somewhat better
5. Much better
6. Missing

Since last contact, have you?
1. Been hospitalized
2. Sought consultation from a health care professional
3. Experienced deterioration of your health without seeking HCP consultation
4. None of the above
5. Missing

If the above question was not "none of the above", was it in relation to the symptoms?
1. Other
2. Similar to the symptoms experienced during COVID-19 hospitalization

Prior to Covid-19 did you work or go to school full time?
1. Yes
2. No

Do you currently work or go to school full time?
1. Yes
2. No

End point type	Post-hoc

End point timeframe:

12 months post-study

End point values	Octagam 10%	Saline Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	84		
Units: participants				
number (not applicable)				
Question 1 - Poor	1	1		
Question 1 - Fair	11	14		
Question 1 - Good	35	36		
Question 1 - Very Good	17	13		
Question 1 - Excellent	2	3		
Question 1 - Missing Answer	18	17		
Question 2 - Much Worse	2	3		
Question 2 - Somewhat Worse	15	12		
Question 2 - The Same	32	44		
Question 2 - Somewhat Better	12	5		
Question 2 - Much Better	5	3		

Question 2 - Missing Answer	18	17		
Question 3 - Been Hospitalized	1	2		
Question 3 - Sought consultation from HCP	29	22		
Question 3 - Experienced deterioration of health	2	0		
Question 3 - None of the above	34	43		
Question 3 - Missing answer	18	17		
Question 4 - Other	27	21		
Question 4 -Similar to those during COVID-19 hosp.	5	5		
Question 5 - Yes	50	44		
Question 5 - No	16	23		
Question 6 - Yes	44	44		
Question 6 - No	22	23		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Approximately 33 Days	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups	
Reporting group title	Octagam 10%
Reporting group description:	
Octagam 10%, 2 g/kg divided by 4 days (0.5 g/kg/day), administered by intravenous infusion over approximately 2 hours per day over 4 consecutive days	
Reporting group title	Saline Solution
Reporting group description:	
Saline solution placebo group	

Serious adverse events	Octagam 10%	Saline Solution	
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 105 (14.29%)	12 / 100 (12.00%)	
number of deaths (all causes)	13	6	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 105 (0.95%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	2 / 105 (1.90%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	0 / 105 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Cerebral haemorrhage			

subjects affected / exposed	1 / 105 (0.95%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic hyperglycaemic coma			
subjects affected / exposed	1 / 105 (0.95%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	3 / 105 (2.86%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	3 / 105 (2.86%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Acute respiratory failure			
subjects affected / exposed	2 / 105 (1.90%)	5 / 100 (5.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 3	
Lung disorder			
subjects affected / exposed	0 / 105 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 105 (0.95%)	0 / 100 (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 / 105 (0.95%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory failure			
subjects affected / exposed	3 / 105 (2.86%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 105 (3.81%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure			
subjects affected / exposed	1 / 105 (0.95%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bacterial Pneumonia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 100 (1.00%)	
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 / 105 (0.95%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal Pneumonia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 105 (0.95%)	3 / 100 (3.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Staphylococcal Pneumonia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral cardiomyopathy			
subjects affected / exposed	0 / 105 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Pneumonia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

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

Non-serious adverse events	Octagam 10%	Saline Solution	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 105 (46.67%)	40 / 100 (40.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	10 / 105 (9.52%)	7 / 100 (7.00%)	
occurrences (all)	10	7	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	10 / 105 (9.52%)	8 / 100 (8.00%)	
occurrences (all)	10	8	
Diarrhoea			
subjects affected / exposed	6 / 105 (5.71%)	7 / 100 (7.00%)	
occurrences (all)	6	7	
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	4 / 105 (3.81%)	6 / 100 (6.00%)	
occurrences (all)	4	6	
Psychiatric disorders			

Anxiety			
subjects affected / exposed	8 / 105 (7.62%)	4 / 100 (4.00%)	
occurrences (all)	8	4	
Insomnia			
subjects affected / exposed	7 / 105 (6.67%)	5 / 100 (5.00%)	
occurrences (all)	7	5	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	7 / 105 (6.67%)	5 / 100 (5.00%)	
occurrences (all)	7	5	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	7 / 105 (6.67%)	4 / 100 (4.00%)	
occurrences (all)	7	4	
Hypokalaemia			
subjects affected / exposed	3 / 105 (2.86%)	6 / 100 (6.00%)	
occurrences (all)	3	6	
Hyponatraemia			
subjects affected / exposed	7 / 105 (6.67%)	4 / 100 (4.00%)	
occurrences (all)	7	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 May 2020	Protocol V3.0 dated 20May2020
08 June 2020	Protocol v4.0 dated 08Jun2020
01 July 2020	Protocol V5.0 dated 01Jul2020
04 August 2020	Protocol V6.0 dated 04Aug2020
18 September 2020	Protocol V7.0 dated 18Sep2020

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported