Clinical trial results:
Senicapoc in COVID-19 Patients with Severe Respiratory Insufficiency – A Randomized, Open-Label, Phase II Trial

Summary

EudraCT number	2020-001420-34
Trial protocol	DK
Global end of trial date	28 December 2020

Results information

Result version number	v1 (current)
This version publication date	21 January 2022
First version publication date	21 January 2022

Trial information

Trial identification

Sponsor protocol code	0001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04594668
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University
Sponsor organisation address	Ole Worms Allé 4, Building 1160, Aarhus C, Denmark, 8000
Public contact	www.Clinicaltrials.gov, Aarhus University, +45 60202613, us@biomed.au.dk
Scientific contact	www.Clinicaltrials.gov, Aarhus University, +45 60202613, us@biomed.au.dk

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	30 September 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 December 2020
Global end of trial reached?	Yes
Global end of trial date	28 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To treat respiratory insufficiency due to COVID19

Protection of trial subjects:

The study was IDMC monitored. Patients were admitted to the ICU and the intervention did not include additional stress or pain

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 April 2020
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	Denmark: 46
Worldwide total number of subjects	46
EEA total number of subjects	46

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)	21
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients were included if they were aged ≥ 18 years and admitted to an ICU with severe respiratory insufficiency due to COVID-19. COVID-19 was defined as a positive polymerase chain reaction (PCR) test for SARS-CoV-2, within 14 days prior to ICU admission. Severe respiratory insufficiency was defined as requiring supplemental oxygen ≥ 10 L/min or m

Period 1

Period 1 title	Entire 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	Control group

Arm description:

Control group

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Senicapoc group

Arm description:

Senicapoc group

Arm type	Experimental
Investigational medicinal product name	Senicapoc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Intragastric use

Dosage and administration details:

The intervention consisted of 50 mg enteral senicapoc (5 x 10 mg tablets) administered as soon as possible after randomization and again after 24 hours.

Number of subjects in period 1	Control group	Senicapoc group
Started	26	20
Completed	26	20

Baseline characteristics

Reporting groups	
Reporting group title	Control group
Reporting group description: Control group	
Reporting group title	Senicapoc group
Reporting group description: Senicapoc group	

Reporting group values	Control group	Senicapoc group	Total
Number of subjects	26	20	46
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Age			
Units: years			
median	66	66	
inter-quartile range (Q1-Q3)	56 to 74	58 to 70	-
Gender categorical			
Gender			
Units: Subjects			
Female	6	10	16
Male	20	10	30

End points

End points reporting groups	
Reporting group title	Control group
Reporting group description: Control group	
Reporting group title	Senicapoc group
Reporting group description: Senicapoc group	

Primary: The PaO2/FiO2 ratio	
End point title	The PaO2/FiO2 ratio
End point description: The PaO2/FiO2 ratio at 72 hours	
End point type	Primary
End point timeframe: at 72 hours	

End point values	Control group	Senicapoc group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	20		
Units: mmHg				
arithmetic mean (standard deviation)	24.4 (± 9.6)	19.5 (± 6.6)		

Statistical analyses

Statistical analysis title	Primary outcome
Comparison groups	Control group v Senicapoc group
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	< 0.05
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	-5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.2
upper limit	0.04

Notes:

[1] - linear regression adjusting for the two stratification variables (baseline PaO2/FiO2 ratio and site) as fixed effects

Secondary: Mortality

End point title	Mortality

End point description:

Mortality

End point type	Secondary

End point timeframe:

28 days

End point values	Control group	Senicapoc group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	20		
Units: %	6	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Ventilator free hours

End point title	Ventilator free hours

End point description:

End point type	Secondary

End point timeframe:

ventilator-free days within 28 days

End point values	Control group	Senicapoc group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	20		
Units: day				
median (inter-quartile range (Q1-Q3))	486 (0 to 672)	607 (398 to 672)		

Statistical analyses

Statistical analysis title	Ventilator free hours
Comparison groups	Senicapoc group v Control group

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Sutdy period	
Assessment type	Systematic

Dictionary used	
Dictionary name	Specific adverse
Dictionary version	1

Reporting groups	
Reporting group title	Control group
Reporting group description: -	
Reporting group title	Senicapoc
Reporting group description: -	

Serious adverse events	Control group	Senicapoc	
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 26 (84.62%)	10 / 20 (50.00%)	
number of deaths (all causes)	6	2	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
arrythmias			
subjects affected / exposed	6 / 26 (23.08%)	2 / 20 (10.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	4 / 26 (15.38%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperglycaemia			
subjects affected / exposed	7 / 26 (26.92%)	5 / 20 (25.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Control group	Senicapoc	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 26 (11.54%)	1 / 20 (5.00%)	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 26 (11.54%)	1 / 20 (5.00%)	
occurrences (all)	3	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported