Clinical trial results:
The Impact of Camostat Mesilate on COVID-19 Infection: An investigator-initiated randomized, placebo-controlled, phase IIa trial

Summary

EudraCT number	2020-001200-42
Trial protocol	DK SE
Global end of trial date	22 April 2021

Results information

Result version number	v1 (current)
This version publication date	18 June 2023
First version publication date	18 June 2023

Trial information

Trial identification

Sponsor protocol code	CamoCO-19-001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04321096
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Blv 99, Aarhus N, Denmark,
Public contact	Ole Schmeltz Søgaard, Department of Infecitous Diseases, Aarhus University Hospital, 0045 23886636, olesoega@rm.dk
Scientific contact	Ole Schmeltz Søgaard, Department of Infecitous Diseases, Aarhus University Hospital, 0045 23886636, olesoega@rm.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	22 April 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 April 2021
Global end of trial reached?	Yes
Global end of trial date	22 April 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The overall objective of the study is to evaluate the efficacy of Camostat Mesilate against COVID-19 infection among adults with COVID-19 infection.

Protection of trial subjects:

Safety will be monitored by vital signs, clinical laboratory tests, history and physical examinations if needed and the rate and severity of AE.

If indicated in the opinion of the investigator, a physical examination will be performed ad hoc. Routine biochemistry (safety) will be performed within +/-12 hours of the first dosing of camostat mesilate. Subsequent dosing will be postponed in case of unacceptable laboratory values in the judgment of the investigator. Laboratory tests may be repeated, as clinically indicated, to obtain acceptable values before participants are withdrawn from the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 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	Sweden: 6
Country: Number of subjects enrolled	Denmark: 199
Worldwide total number of subjects	205
EEA total number of subjects	205

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)	116
From 65 to 84 years	79
85 years and over	10

Subject disposition

Recruitment

Recruitment details:

The site PI (physician) or delegated study physician/nurse will obtain written informed consent from each subject before any study-specific activity is initiated, using a consent form prospectively approved by The Ethics Committee.

Pre-assignment

Screening details:

Less than 48 hours since time of hospital admission OR if hospital-acquired COVID-19 is suspected, less than 48 hrs since onset of symptoms

Period 1

Period 1 title	Dosing/follow-up (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
Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

x3 daily for 5 days

Arm title	Camostat

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Camostat mesilate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200 mg x3 daily for 5 days

Number of subjects in period 1	Placebo	Camostat
Started	68	137
Completed	68	137

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Camostat
Reporting group description: -	

Reporting group values	Placebo	Camostat	Total
Number of subjects	68	137	205
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 Units: years			
median	61	62	
inter-quartile range (Q1-Q3)	55 to 74	51 to 75	-
Gender categorical Units: Subjects			
Female	27	55	82
Male	41	82	123
Viral load Units: copies/ml			
arithmetic mean	4.9	4.6	
standard deviation	± 1.7	± 1.8	-

End points

End points reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Camostat
Reporting group description: -	

Primary: Clinical improvement	
End point title	Clinical improvement
End point description:	
End point type	Primary
End point timeframe:	
30 daus	

End point values	Placebo	Camostat		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	68	137		
Units: days				
median (inter-quartile range (Q1-Q3))	5 (2 to 10)	5 (3 to 7)		

Statistical analyses

Statistical analysis title	Kaplan-Meier
Comparison groups	Placebo v Camostat
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.3107
Method	Logrank

Secondary: During of oxygen supplementation	
End point title	During of oxygen supplementation
End point description:	
End point type	Secondary
End point timeframe:	
30 days	

End point values	Placebo	Camostat		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	68	137		
Units: days				
median (inter-quartile range (Q1-Q3))	4 (2 to 8)	4 (2 to 7)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 days	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.03

Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Camostat
Reporting group description: -	

Serious adverse events	Placebo	Camostat	
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 68 (11.76%)	27 / 137 (19.71%)	
number of deaths (all causes)	4	8	
number of deaths resulting from adverse events	4	8	
Investigations			
Death			
subjects affected / exposed	4 / 68 (5.88%)	8 / 137 (5.84%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 8	
Blood and lymphatic system disorders			
Thromboembolic event			
subjects affected / exposed	0 / 68 (0.00%)	3 / 137 (2.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnea			
subjects affected / exposed	3 / 68 (4.41%)	4 / 137 (2.92%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			

subjects affected / exposed	1 / 68 (1.47%)	2 / 137 (1.46%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Lung infection			
subjects affected / exposed	0 / 68 (0.00%)	6 / 137 (4.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 68 (0.00%)	1 / 137 (0.73%)	
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: 0 %

Non-serious adverse events	Placebo	Camostat	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 68 (4.41%)	3 / 137 (2.19%)	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 68 (1.47%)	2 / 137 (1.46%)	
occurrences (all)	1	2	
Diarrhoea			
subjects affected / exposed	2 / 68 (2.94%)	1 / 137 (0.73%)	
occurrences (all)	2	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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/3390385