



## 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             |
| 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 Infectious Diseases, Aarhus University Hospital, 0045 23886636, olesoega@rm.dk |
| Scientific contact           | Ole Schmeltz Søgaard, Department of Infectious 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     |
| <b>Arm title</b>             | 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

|                  |          |
|------------------|----------|
| <b>Arm title</b> | 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<br>Units: Subjects                    |          |          |       |
| In utero  |          |          | 0     |
| Preterm newborn infants<br>(gestational age < 37 wks) |          |          | 0     |
| Newborns (0-27 days)                                  |          |          | 0     |
| Infants and toddlers (28 days-23<br>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<br>Units: years                        |          |          |       |
| median  | 61       | 62       |       |
| inter-quartile range (Q1-Q3)                          | 55 to 74 | 51 to 75 | -     |
| Gender categorical<br>Units: Subjects                 |          |          |       |
| Female  | 27       | 55       | 82    |
| Male  | 41       | 82       | 123   |
| Viral load<br>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                |                                  |

| <b>End point values</b>               | 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           |  |
| <b>Infections and infestations</b>              |                |                 |  |
| 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 %

| <b>Non-serious adverse events</b>                     | Placebo        | Camostat        |  |
|---|----------------|-----------------|--|
| Total subjects affected by non-serious adverse events |                |                 |  |
| subjects affected / exposed                           | 3 / 68 (4.41%) | 3 / 137 (2.19%) |  |
| <b>Gastrointestinal disorders</b>                     |                |                 |  |
| 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

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

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