Trial synopsis

English

Title of clinical Trial	The DAWN camostat trial: the efficacy of camostat for COVID-19 infections presenting to ambulatory care: a randomized controlled trial.
Protocol Short Title Acronym	The DAWN camostat trial for ambulatory COVID-19 patients
Trial Phase (I, II, III, IV)	Phase III
Sponsor name	KU Leuven represented by UZ Leuven
Coordinating Investigator	Ann Van den Bruel
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Trial permancy /emergency contact	
Contact email	dawn.camostat@gmail.com
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EudraCT number	2020-005911-27
Other public database nbr	
Principal Investigators and Participating Sites	
Medical condition or disease under investigation	COVID-19
Trial rationale	Treatment with camostat of patients with COVID-19 in ambulatory care may improve patient prognosis and decrease pressure on health care services
Primary objective	Assess the efficacy of camostat on recovery, hospital admission or mortality over 30 days after randomisation
Secondary objective(s)	Assess the efficacy of camostat on symptoms, cardiovascular events, severity, health care utilisation and quality of life over 30 days after randomisation, and all-cause mortality at 1 year after randomisation.
Trial Design	Prospective, placebo controlled, individually randomised trial
In- and exclusion criteria	Inclusion criteria: - Aged 40 years or older; - At least 2 Covid-19 suggestive symptoms at the time of inclusion, with onset of a maximum of 5 days prior to enrolment; - Positive result on a PCR test or rapid Ag test in the 7 days before inclusion or at the time of inclusion in the study; - Patient is community dwelling; - Participant or their proxy is willing and able to give informed consent for participation in the trial; - Participant is willing to comply with all trial procedures.

<table>
<tr><td></td><td>Exclusion criteria:
- Hospital admission is required at the time of possible recruitment;
- Positive PCR or rapid antigen test for SARS-CoV-2 in the last 2 months other than in the 7 days prior to recruitment;
- Participating in any other interventional drug clinical study before enrolment in the study;
- Known severe neurological disorder, especially seizures in the last 12 months;
- Known allergy to camostat;
- Previous adverse reaction to, or currently taking, camostat;
- Patients in palliative care; Pregnant women or women of childbearing potential who may become pregnant during the trial;
- Judgement of the recruiting clinician deems participant ineligible.</td></tr>
<tr><td>Outcomes</td><td>Two co-primary endpoints
First co-primary endpoint: first self-reported recovery
Second co-primary endpoint: all-cause unplanned hospital admission for at least 24 hours or all-cause mortality within 30 days after randomisation.
Secondary endpoints
- Time to sustained recovery within 14 days = time from randomization to self-reported recovery within 14 days and remaining recovered until day 30 after randomisation.
- All-cause unplanned hospital admission for at least 24 hours within 30 days after randomisation.
- All-cause mortality within 30 days after randomisation;
- WHO clinical progression scale at 8 days and 30 days after randomisation
<table>
<tr><td>0</td><td>Uninfected</td></tr>
<tr><td>1</td><td>Ambulatory, asymptomatic</td></tr>
<tr><td>2</td><td>Ambulatory, symptomatic independent</td></tr>
<tr><td>3</td><td>Ambulatory, symptomatic, assistance needed</td></tr>
<tr><td>4</td><td>Hospitalized, no oxygen therapy</td></tr>
<tr><td>5</td><td>Hospitalized, oxygen by mask or nasal prongs</td></tr>
<tr><td>6</td><td>Hospitalized, oxygen by NIV or high flow</td></tr>
<tr><td>7</td><td>Hospitalized, intubation and mechanical ventilation $pO_2/FiO2 \geq 150$ or $SpO_2/FiO_2 \geq 200$</td></tr>
<tr><td>8</td><td>Hospitalized, mechanical ventilation $pO_2/FiO_2 < 150$ or vasopressors</td></tr>
<tr><td>9</td><td>Hospitalized, mechanical ventilation $pO_2/FiO_2 < 150$ and vasopressors, dialysis or ECMO</td></tr>
<tr><td>10</td><td>Dead</td></tr>
</table>
- At least once oxygen administration over a period of 30 days after randomisation;</td></tr>
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	- At least once ventilated over a period of 30 days after randomisation; - Admission to ICU over a period of 30 days after randomisation; - All-cause mortality at 1 year after randomisation; - Cardiovascular and thromboembolic complications within 7 days and 30 days after randomisation; - Symptom duration for each individual symptom over a period of 30 days after randomisation; - Duration of hospital admission for those admitted to hospital over a period of 30 days after randomisation; - Number of contacts with health services including general practitioners, out-of-hours services, emergency department visits, specialist assessments over a period of 30 days after randomisation; - Number of hospital assessments without admission over a period of 30 days after randomisation; - Consumption of antibiotics over a period of 30 days after randomisation, expressed in defined daily dose; - Quality of life as measured by the EQ-5D-5L at 7 days and 30 days after randomisation.
Sample Size	1316 (658 in each treatment group)
IMP, dosage and route of administration	Camostat, 200 mg four times a day, for 7 days, oral tablet
Active comparator product(s)	Placebo
Maximum duration of treatment and Follow Up of a Participant	- 7 days of treatment - 30 days of follow-up for most endpoints - 1 year follow-up for all-cause mortality
Maximum duration of entire Trial	15 months
Date anticipated First Participant First Visit (FPFV)	17 May 2021
Date anticipated Last Patient Last Visit (LPLV)	31 August 2022