Do you need help?
Call the HOT-COVID hotline
+45 21 18 25 43
Available 24/7

OR

hot-covid@cric.nu

Queries? Please contact:

hot-covid@cric.nu

Thomas Lass Klitgaard, coordinating investigator
Phone: +45 97 66 18 70

Bodil Steen Rasmussen, sponsor
Phone: +45 97 66 18 64

HOT-COVID

Handling Oxygenation Targets COVID-19 (HOT-COVID)

Information for health care professionals

Your department enrols patients in
The HOT-COVID Trial

The HOT-COVID Trial compares two separate targets of partial pressure of arterial oxygen (PaO_2) in guiding oxygen administration in critically ill patients

The HOT-COVID Trial enrols 780 patients admitted to European intensive care units (ICUs)

The HOT-COVID Trial is supported by public funding

The HOT-COVID Trial is approved by all relevant authorities

HOT-COVID

Clinicians' role in HOT-ICU

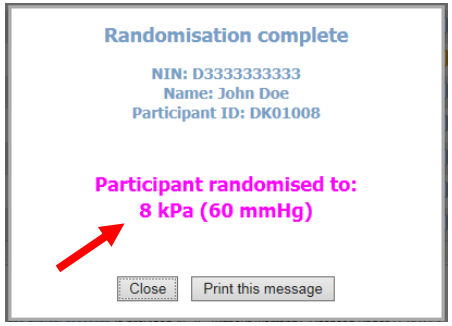
Screening

When a patient is admitted to the ICU please evaluate the patient for inclusion in the trial. If all inclusion criteria are fulfilled, the ICU physician on duty is requested to screen the patient at www.cric.nu/hot-covid. Even though one or more exclusion criteria are met, we kindly ask you to complete the screening procedure.

Randomisation (by physician)

Remember to obtain consent according to your national regulations before randomisation (if required).

Complete the screening procedure. If the patient fulfils the inclusion criteria and no exclusion criteria are met, you will get the opportunity to randomise the patient.
Click 'Perform randomisation'. A window with the allocated oxygenation target will appear (PaO_2 of 8.0 kPa or 12.0 kPa).



Print or write down the oxygenation target. If you wish to confirm the allocated oxygenation target you can find it at the bottom of the screening form or in an email, which is sent to you upon randomisation, the email is sent to the email address you used for registration.
Adjust the FiO_2 to achieve the allocated oxygenation target immediately after completed randomisation.
Prescribe the allocated oxygenation target in the patient's ICU chart and write a note in the patient's medical journal stating inclusion of the patient in the HOT-ICU trial as well as the allocated oxygenation target.

During the ICU stay

The allocated oxygenation target of a PaO_2 of 8.0 kPa or 12.0 kPa should be upheld for as long as the patient is admitted to the ICU (maximum 90 days). If the patient is discharged and readmitted to the ICU, please continue the allocation.

FiO_2 is titrated from 0.21 to 1.00 to achieve the allocated oxygenation target in both interventional groups.

The allocated oxygenation target should be upheld at all means possible during transportation, radiological examination and surgical procedures. However, the oxygen supplementation and required oxygenation during these procedures will be at the discretion of the treating clinicians.

Concerning other procedures conducted within the ICU (endotracheal suctioning, mobilisation, bronchoscopy etc.), oxygen supplementation that exceeds the allocated oxygenation target in both interventional groups should be restricted to the minimally required. Preoxygenation with an FiO_2 of 1.00 during endotracheal procedures should be avoided if at all possible. If not, the FiO_2 may be increased up to 1.00 for a maximum duration of 1 minute prior to endotracheal suctioning and for a maximum duration of 3 minutes prior to intubation at the discretion of the treating clinicians.

Aside from the oxygenation target and the oxygen supplementation needed to achieve this, patient management will be unaffected of trial participation.

Information about HOT-COVID

Background

Acutely ill adults with SARS-CoV-2 (COVID-19) and hypoxaemic respiratory failure admitted to the ICU are at risk of life-threatening hypoxia and thus oxygen is administered. However, the evidence on the optimal level of oxygenation is of low quantity and quality with no firm evidence for benefit or harm. Importantly, liberal use of supplementary oxygen may increase the number of serious adverse events including death.
The aim of the HOT-COVID trial is to assess benefits and harms of two targets of PaO_2 in guiding the oxygen administration in acutely ill adult ICU patients with COVID-19 and hypoxaemic respiratory failure, hereby improving the evidence of optimal targets of oxygenation within the ICU.

Methods

In total 780 patients admitted to European ICUs will be randomised to a PaO_2 target of

either
- **8.0 kPa**

or
- **12.0 kPa**

Throughout the duration of the ICU stay, including readmissions up until maximally 90 days after randomisation.

Results

At the end of the trial we will calculate the 90-day mortality and days alive without life-support, days alive and out of hospital, and the incidences of new episode of cardiac ischaemia, gastrointestinal ischaemia, ischaemic stroke, and shock within the 90-day period.

Funding

The trial has a budget of approx. 5 million Danish kroner (0.7 million Euro) and is funded by the Danish Ministry of Higher Education and Science

The full protocol is available at

www.cric.nu/hot-covid

Manuals

The trial manuals and other relevant documents are available at www.cric.nu/hot-covid (trial documents)

Queries?

If you have any queries do not hesitate to contact coordinating investigator Thomas Lass Klitgaard. See contact information at the back of this leaflet.