



Place in Site Master File #9a

Instruction for the HOT-COVID trial – screening and randomisation

Please screen all adults meeting the inclusion criteria (admitted acutely to the ICU, receiving oxygen supplementation above the defined criteria, are expected to receive oxygen supplementation within the ICU for at least 24 hours, have an intra-arterial catheter AND are SARS-CoV-2 positive) to assess their eligibility for inclusion in HOT-COVID. A screening log is maintained to monitor patient recruitment at each site and will enable a description of the patient population from which eligible patients have been enrolled. All patients will be allocated a site specific 'Trial participant ID' when initiating the screening procedure.

1. Go to www.cric.nu/hot-covid
Click the eCRF link to 'Screen, randomise and enter data'



Handling Oxygenation Targets in COVID-19

Hotline: **+45 21 18 25 43**



Screen, randomise, and enter data



Trial documents

2. Login to the eCRF with your personal login. If you have not received your login, please send an e-mail to hot-covid@cric.nu, or use the HOT-COVID hotline +45 2118 2543



3. Click the 'Go to patient screening' button

For Screening click here: [Go to Patient Screening](#) For Site overview click here: [Site Overview](#)

Trial Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Daily Form	Discharge and readmission	Withdrawal	Follow-Up 90 days	Follow-Up 1 year	Actions
DK01006	Olav Test8	D0000000000	01-06-2017	✓	📄	📄	✓	📄	📄	📄	Click here to enter data
DK01005	<Name not defined>	<NIN not defined>	31-05-2017	📄	📄	📄	📄	📄	📄	📄	Click here to enter data
DK01004	Olav test7	D6666666666	30-05-2017	✓	📄	📄 x2	📄	📄	📄	📄	Click here to enter data
DK01003	Olav Test6	D5555555555	30-05-2017	✓	📄	📄 x2	📄	📄	📄	📄	Click here to enter data
DK01001	Janus #1	0501771163	22-05-2017	✓	📄	📄 x10	📄	📄	📄	📄	Click here to enter data

Results 1 - 5 of 5.

4. A national identification number (NIN) is needed to help identifying the patient

Danish sites:

- Enter the CPR number in Danish participants
- If a fictive CPR number has been constructed **use the letter D** as a prefix to override the check of a valid CPR number

In all other countries, NIN has to be constructed

NIN is a unique number identifying the patient and will be checked by the system to make sure the same patient is not randomised more than once. The NIN consists of:

- Date of birth (ddmmyy) (for Switzerland 0101+year)
- A site identifier (automatically generated)
- A serial number. Enter 01

If a warning appears (see below), please check that the patient has not previously been enrolled

WARNINGS: two types of warnings are possible:

Red warning: The NIN is completely identical with a previously constructed NIN. If it is NOT the same patient, **please change the serial number to 02**

Yellow warning: The NIN is partly identical to a previously constructed NIN. If the name of the patient does not appear on the list shown, please press 'accept' and continue


SCREENING FORM		
		Support: mail or +45 1234 5678
Patient Identification		
S1	National identification number	<input type="text"/> [info]
Inclusion criteria		
S2	Acutely admitted to the ICU?	<input type="radio"/> Yes <input type="radio"/> No [info]
S3	Age ≥ 18 years?	<input type="radio"/> Yes <input type="radio"/> No
S4	Respiratory support in a closed system independent of FiO ₂ OR oxygen supplementation in an open system with at least 10 L oxygen per minute?	<input type="radio"/> Yes <input type="radio"/> No [info]
S5	Oxygen supplementation in the ICU expected to last for at least 24 hours? <i>(If in doubt of this forecast answer 'YES')</i>	<input type="radio"/> Yes <input type="radio"/> No [info]
S6	Intraarterial catheter in place?	<input type="radio"/> Yes <input type="radio"/> No [info]
S7	Positive test for coronavirus?	<input type="radio"/> Yes <input type="radio"/> No [info]

5. Complete the screening form

Note that fertile women (defined as age <50 years) have to have a negative pregnancy test before screening and that consent according to national regulations **always** has to be obtained


When the form is complete the text in the randomisation window will change to either **green** (eligible) or **red** (not eligible)

Patient is eligible for inclusion.
Fill in name and click 'Perform randomisation' button.



Stratification and randomisation

S20	Name of the patient	<input type="text" value="John Doe"/>	<input type="checkbox"/> Unknown at the time of screening
S21	Site ID	<input type="text" value="DK01"/>	
<input type="button" value="Perform randomisation"/>			
R1	Participant randomised to	<input type="text"/>	
R2	Randomisation timestamp	<input type="text"/>	



6. Make sure all answers are correct.

If the patient is eligible for randomisation enter the name of the patient (Switzerland: initials only). If unknown the name and correct birthdate can be added later on during the trial. This will help you identify the patient when entering data

7. When the form is complete 'Perform randomisation' will be active. Click the button

The patient has now been randomised and the allocated oxygenation target will be highlighted

Randomisation complete

NIN: D1111111111
Name: John Doe
Participant ID: DK01012

**Participant randomised to:
12 kPa (90 mmHg)**

You can save/find the allocated oxygenation target by

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- printing the message
- opening the email send to the email account used when signing up
- opening the screening form. The oxygenation target will be visible in the randomisation window

Participant is randomised to 12 kPa (90 mmHg)

Stratification and randomisation	
S20	Name of the patient <input type="text" value="John Doe"/> [info]
S21	Site ID <input type="text" value="DK01"/>
R1	Participant randomised to <input type="text" value="12 kPa (90 mmHg)"/>
R2	Randomisation timestamp <input type="text" value="2020-08-14 13:35:37"/>

8. Adjust the FiO₂ to achieve the allocated oxygenation target

- Prescribe the allocated oxygenation target in the patient's ICU chart
- 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

The allocated oxygenation target should be upheld throughout the duration of the ICU stay, including readmissions up until maximally 90 days after randomisation