Daily clinical screening

Every morning

Clinicians point out new eligible patients who fullfill **all** inclusion criteria

All patients fulfilling **all** inclusion criteria must be screened in eCRF

But first…

Informed consent

It is legal to include **inhabited** participants in clinical trials if **surrogate consent** is obtained (Komitéloven §4)

All patients with COVID-19 and severe hypoxia will be temporarily incompetent

- Acute illness
- Low oxygen saturation
- Stress-response associated with lack of oxygen

The first trial guardian (doctor)

- independent of the trial
- knowledge of the clinical condition
- familiar with the trial protocol

Informed consent

Procedure

1. Obtain **informed consent** from the **first trial guardian before** randomisation (oral consent by telephone is permitted**)**

2. Note **date, time and name of first trial guardian** in electronic medical journal

3. Obtain **written consent** from the first trial guardian by post or e-mail as soon as possible

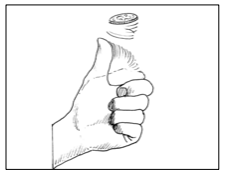
After consent – screen & include

Log into the electronic medical journal

Screening of inclusion and exclusion criteria for new eligible patients

Log on to the web based eCRF

Screening of inclusion and exclusion criteria



Randomisation

Informed consent is obtained from first trial guardian

AND

Patient fulfill **all** inclusion criteria and **none** of the exclusion criteria

THEN

Randomise the patient in the web based eCRF

Informed consent

Next of kin and second trial guardian

Obtain consent **as soon as possible** from the **next of a kin by phone** and a **second trial guardian**

- **Next of kin** is defined as relatives, friends or other acquaintances in regular contact with the trial partcipant
- **Second trial guardian** must fulfill the same criteria as the first trial guardian

Trial participant

Consent must be obtained as soon as patient regains competence, preferably during admission

http://www.nvk.dk/emner/information-og-samtykke-i-forsoeg/vejledning-om-samtykke-i-forsoeg

Screen, randomise and enter data

www.cric.nu/covid-steroid-2-trial