COVID STEROID 2 interim analysis
IDMSC recommendation

The interim analysis was conducted on **March 12, 2021**, by the Independent Data Monitoring and Safety Committee (IDMSC).

The IDMSC is formed by:

- Christian Hassager
  Professor in cardiology, Rigshospitalet, University of Copenhagen, DK
- Manu Shankar-Hari
  Clinician Scientist, Reader and Consultant in Intensive Care Medicine, National Institute for Health Research and Kings College, London, UK
- Susanne Rosthøj
  Department of Biostatistics, University of Copenhagen)

The recommendation from the IDMSC was as follows:

"We reviewed the summary data presented to us based on 500 randomised patients. We noted that there were NO

a) differences in adverse effect profile/ safety issues raised

b) major signal to change the course of the trial

We then considered any external evidence of relevance to this trial. We felt that there was NO external evidence to change the course of the trial.

Given above, DSMB unanimously agreed to strongly recommend continuation of the trial. We also acknowledge that there will be no further interim analysis."

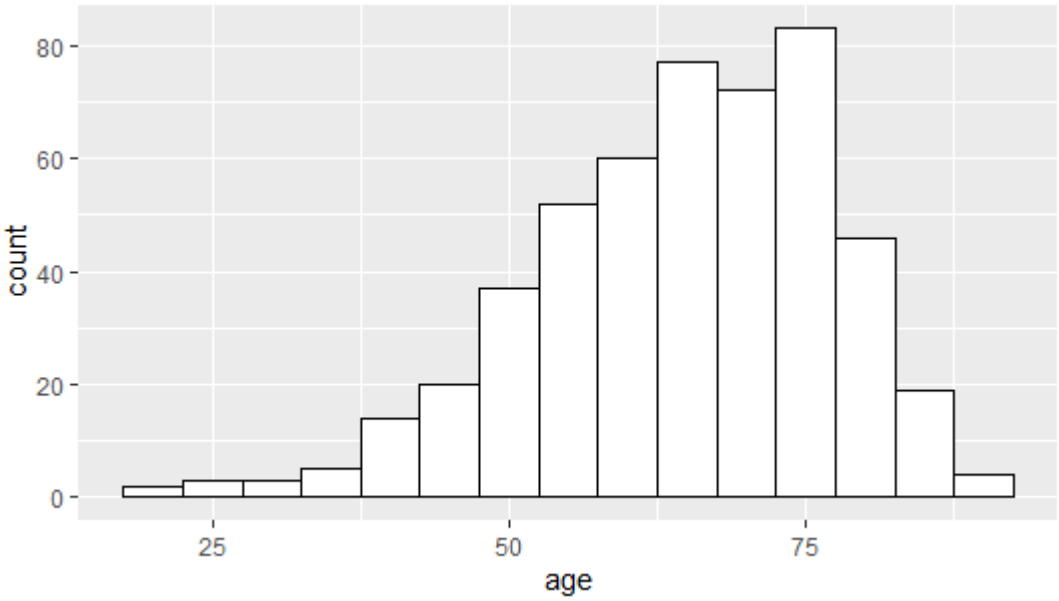
Sponsor Anders Perner has, based on the recommendation above, decided to continue enrolment in the COVID STEROID 2 trial.

Descriptive data from the interim analysis of the first 500 enrolled participants followed for 28 days in the COVID STEROID 2 trial

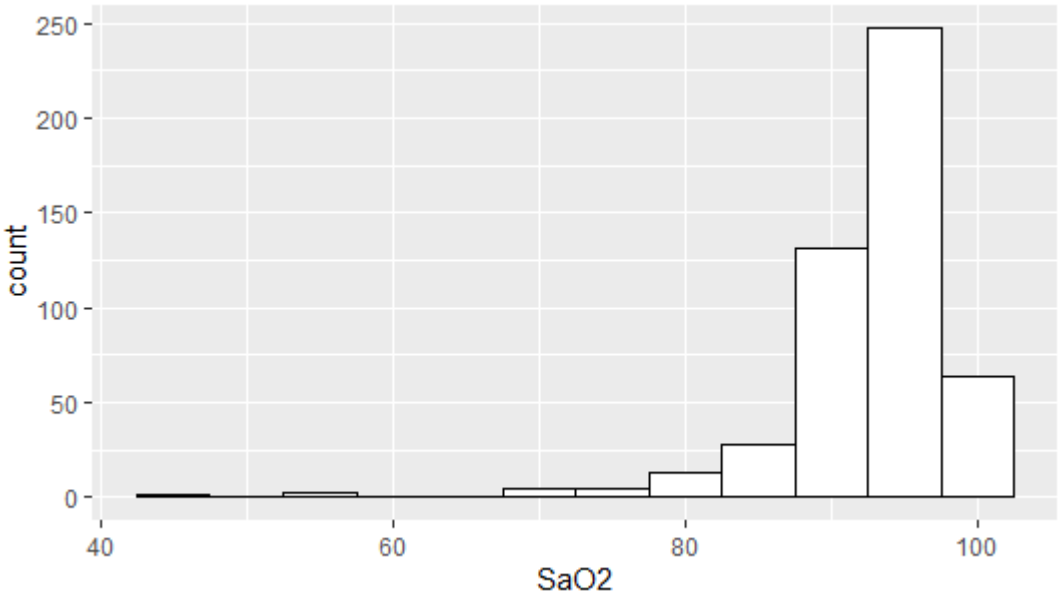
Only the DMSC has analysed data separately for the two allocation groups.

Baseline characteristics	**Proportion**
Male gender	70%
Chronic use of steroids	3%
Limitations in care	8%
Respiratory support via a closed system at randomization (CPAP, NIV, iMV)	44%
Use of invasive mechanical ventilation at randomization	24%
Outcomes at day 28	
One or more Serious Adverse Reaction	15%
Mortality	30%

Age at randomisation for the 500 patients included in the interim analysis



SaO2 at baseline for the 500 patients included in the interim analysis



Plot of days alive without life support at day 28 (primary outcome) for the 500 patients included in the interim analysis