COVID-19-HBO Multicenter Trial Invitation

We are inviting hyperbaric centers with experience in and recourses available for critically ill patients to a randomized controlled, open label multicenter trial designed to examine the safety and efficacy of hyperbaric oxygen for COVID-19. This trial has been approved by the Swedish Independent Ethics committee (EPM) and approved by Swedish Medicinal Products Agency (MPA) and details are published on clinicaltrials.gov/NCT04327505, Sponsor is Karolinska Institutet, Solna, Sweden Hyperbaric medicine, KI.

The full details of this trial, "A Randomized, Controlled, Open Label, Multicentre Clinical Trial to explore Safety and Efficacy of Hyperbaric Oxygen for preventing ICU admission, Morbidity and Mortality in Adult Patients With COVID-19" will be sent on request. In summary:

Prospective randomized, open label, multi-centre, estimated enrolment: 200 subjects.

Study population: adults with moderate COVID-19 admitted to hospital requiring oxygen and at least two risk factors for increased morbidity/mortality.

Intervention: Hyperbaric oxygen (HBO) in addition to best practice. HBO: 1.6-2.4 ATA for 30-60 min, maximum 5 treatments within 7 days from inclusion

Control: Best practice for COVID-19 pneumonitis

Primary endpoint: ICU admission (defined by specific criteria)

Main secondary endpoints: 30-day mortality, Time-to-Intubation, Time-to-ICU, Mean change in inflammatory response, Overall Survival

Safety and other endpoints in selection: Adverse events, Change in vital parameters (NEWS), Change in oxygen requirement (PFI)

Data will be entered online, using SmartTrial® and randomization will be made online with Randomize.NET. We will support investigators with the paperwork for national regulatory bodies, information and education to set up your department as a site in this trial but expect each site to carry most of their own costs for including subjects. All contributing investigators will be recognized in the subsequent publication of our results. We look forward to your review of this trial and are readily available for communication. Please contact Coordinating investigator Anders Kjellberg anders.kjellberg@ki.se, +46760657355 if you interested in participating so that we can send you the full protocol and other information.

We look forward to hearing from you and await your response with anticipation.

Respectfully,

ANDERS KJELLBERG, MD, DESA, EDIC