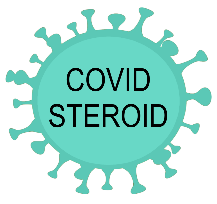
COVID-STEROID\_vs1.2\_4May2020



Site Master File COVID STEROID Trial

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| **1.** | **Protocol and trial synopsis**   1. Approved protocol 2. Approved amendments 3. Trial synopsis 4. Front page [to be signed by Primary Investigator](http://cric.nu/covid-steroid-front-page) |
| **2.** | **eCRF** |
| **3.** | **Trial participants**   1. Delegation-and signature log 2. Training log and training log signed by Sponsor for [primary investigators](http://cric.nu/covid-steroid-training-log-signed-by-sponsor-for-primary-investigators) and [primary trial personnel](http://cric.nu/covid-steroid-training-log-signed-by-sponsor-for-primary-trial-personnel) 3. Curriculum Vitae for all personnel |
| **4.** | **Approvals and correspondence**   1. The Danish Medicine Agency 2. EudraCT 3. The Committees on Health Research Ethics, including approved amendments 4. The Capital Region Knowledge Center for Data Compliance 5. National and local approvals 6. Annual Safety Report |
| **5.** | **Collaboration agreement**   1. Collaboration agreement between Sponsor and site 2. Approval from head of department 3. Other relevant contracts |
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