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
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| **5.** | **Collaboration agreement**1. Collaboration agreement between Sponsor and site
2. Approval from head of department
3. Other relevant contracts
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| **6.** | **Financial affairs**1. Case money
2. Patient insurances
 |
| **7.**  | **Information to participants**1. Trial information
2. Consent forms
3. Further data registration form
4. The rights of the patient in clinical research
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| **8.** | **Co-enrolment and substudies**1. Co-enrolment Form and Co-enrolment List
2. Quality criteria for substudies
3. Substudy proposal form
 |
| **9.**  | **Trial documents**a) Trial instructions1. Eligibility
2. Screening and randomisation
3. Trial medication, co-interventions and concomitant interventions
4. eCRF
5. SAE, SUSAR and unblinding

b) Pocket cards, documents for a notice board in the department1. Trial medication for notice board
2. Inclusion and exclusion criteria for notice board
3. Trial synopsis for notice board
4. Pocket cards
5. Leaflet for clinician staff
6. Sign for bed

c) Educational material (power point presentations)1. Initiation for primary investigators and primary trial personnel
2. Screening and randomisation
3. Trial medication
4. Data entry
5. Withdrawal
6. SAE/SUSAR and unblinding

d) Procedures1. [Approved procedures by sponsor](http://cric.nu/covid-steroid-approved-procedures)
2. [How to randomise a patient if system failure occur](http://cric.nu/covid-steroid-trial-documents-system-failure)? and [Screening formula for randomisation during system failure](http://cric.nu/screening-formula-for-randomisation-during-system-failure)
3. [Procedure for obtaining consent](http://cric.nu/covid-steroid-procedure-for-obtaining-consent)
 |
| **10.** | **Trial Medication**1. Labels for infusion and bolus injections
2. Summary of product characteristics for Saline and Hydrocortisone
3. Trial Medication log
4. Video instructions (not to be printed) and guide for trial medication preparation
 |
| **11.** | **Laboratory tests** [not applicable in COVID-STEROID Trial] |
| **12.** | **Primary data source** |
| **13.** | **Communication**1. Contact details – Management Committee
2. Contact details – participating sites
3. Note to file send to Sponsor (template)
4. Note to file received from Sponsor (template)
5. Other correspondences between Sponsor and site(s) (site specific)
6. News letters
7. Correspondence to all sites (e-mails)
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| **14.** | **Serious adverse events and suspected unexpected serious adverse reactions**1. SAE/SUSAR report form
2. Documentation for reporting of SAE/SUSAR
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| **15.**  | **GCP unit**1. Contacts (monitors/GCP units) (site specific)
2. Monitoring visits
3. Monitoring reports (site specific)
4. Monitoring plan and [data verification plan](http://cric.nu/covid-steroid-data-verification-plan)
5. Approval of trial initiation (site specific)
6. Correspondence with the monitor (e.g. GCP unit) (site specific)
7. Collaboration agreement between sponsor and GCP-unit
8. Training from GCP to Primary Investigators
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| **16.** | **Trial completion** |
| **17.** | **Appendices**1. 1-year follow-up questionnaire
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