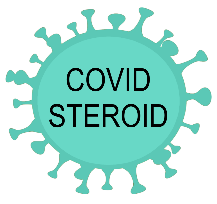
COVID-STEROID\_vs1.0\_14Apr2020



Site Master File COVID STEROID Trial

Table of content

|  |  |
| --- | --- |
| **1.** | **Protocol and trial synopsis**   1. Approved protocol 2. Approved amendments 3. Trial synopsis 4. Front page |
| **2.** | **eCRF** |
| **3.** | **Trial participants**   1. Delegation-and signature log 2. Training log 3. Curriculum Vitae for all personnel |
| **4.** | **Approvals and correspondence**   1. The Danish Medicine Agency 2. EudraCT 3. The Committees on Health Research Ethics 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 |
| **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 5. Procedure for obtaining consent |
| **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 instructions   1. Eligibility 2. Screening and randomisation 3. Trial medication, co-interventions and concomitant interventions 4. eCRF 5. SAE/SUSAR   b) Pocket cards, documents for a notice board in the department   1. 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 2. Screening and randomisation 3. Trial medication 4. Data entry 5. Withdrawal 6. SAE/SUSAR and un-blinding |
| **10.** | **Trial Medication**   1. Labels 2. Summary of product characteristics 3. Trial Medication log |
| **11.** | **Laboratory tests** [not applicable in COVID-STEROID Trial] |
| **12.** | **Primary data source** |
| **13.** | **Communication**   1. Contact details – Steering Committee 2. Contact details – participating countries 3. Note to file send to Sponsor 4. Note to file received from Sponsor (template) 5. Other correspondences between Sponsor and site(s) (site specific) 6. News letters 7. Correspondence |
| **14.** | **Serious adverse events and suspected unexpected serious adverse reactions**   1. SAE/SUSAR report form 2. Documentation for reporting of SAE/SUSAR |
| **15.** | **GCP unit**   1. Contacts (monitors/GCP units) (*site specific)* 2. Monitoring visits 3. Monitoring reports (*site specific)* 4. Monitoring 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 |
| **16.** | **Trial completion** |
| **17.** | **Appendices**   1. 1-year follow-up questionnaire |