

Site master file SUP-ICU

EudraCT number 2015-000318-24

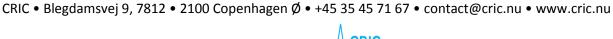
Table of contents

- 1) Protocol and trial synopsis
 - a) Approved protocol
 - b) Approved amendments
 - c) Trial synopsis
- 2) CRF
- 3) Trial participants
 - a) Delegation- and signature log
 - b) Training log
 - c) Curriculum Vitae for all personnell
- 4) Approvals and correspondence
 - a) The Danish Health and Medicines Authority
 - b) EudraCT
 - c) The Committees on Health Research Ethics
 - d) The Danish Data Protection Agency (Datatilsynet)
 - e) National and local approvals
 - f) Annual Safety Report
- 5) Collaboration agreement
 - a) Collaboration agreement between Sponsor and site
 - b) Approval from head of department
 - c) Other relevant contracts
- 6) Financial affairs
 - a) Case money
 - b) Patient insurances (where relevant)

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- 7) Information to paticipants
 - a) Patient information
 - b) Consent forms
- 8) Co-enrolment og substudies
 - a) Co-enrolment form
 - b) Quality criteria for substudies
 - c) Substudy proposal form
- 9) Trial documents
 - a) Trial instructions
 - i) Eligibility
 - ii) Screening and randomisation
 - iii) Trial medication
 - iv) eCRF
 - v) SAR/SUSAR
 - b) Pocket cards, documents for a notice board in the department
 - i) Trial medication for notice board
 - ii) Inclusion and exclusion criteria for notice board
 - iii) Trial synopsis for notice board
 - iv) Pocket cards
 - v) Leaflet for clinicians/nurses
 - vi) Sign for bed
 - vii) Identification log
 - c) Educational material (power point presentations)
 - i) Background
 - ii) Screening and randomisation
 - iii) Trial medication
 - iv) Data entry
 - v) Withdrawal
 - vi) SAR/SUSAR and undblinding
 - vii) Information for nurses
- 10) Trial medication
 - a) Labels
 - b) Summary of product characteristics
 - c) Drug disposal form



- d) Receipt of trial medication
- e) Instruction for temperature logger
- 11) Laboratory tests
- 12) Primary data source
- 13) Communication
 - a) Contact details Steering Committee
 - b) Contact details Denmark, Finland, Netherlands, Norway, UK, Italy, Switzerland
 - c) Note to file send to Sponsor
 - d) Note to file received from Sponsor
 - e) Other correspondances between Sponsor and site(s)
 - f) News letters
 - g) Investigator meeting
- 14) Serious adverse reactions and suspected unexpected serious adverse reactions
 - a) SAR/SUSAR form
 - b) Documentation for reporting of SAR/SUSAR
- 15) GCP unit
 - a) Contacts (monitors/GCP units)
 - b) Monitoring visits
 - c) Monitoring reports
 - d) Monitoring plan
 - e) Approval of trial initiation
 - f) Correspondance with the monitor (e.g. GCP-unit)
- 16) Trial completion

