**Kildedataliste**

**Protokoltitel:** Agents Intervening Against Delirium in the Intensive Care Unit (AID-ICU)

**Afdeling:**

**Hospital:**

**Investigator:**

|  |  |
| --- | --- |
| **Data** | **Primary data source** |
| Consent |  |
| **SCREENING FORM** |  |
| Participant ID |  |
| **INCLUSION CRITERIA** |  |
| Delirium  |  |
| Age |  |
| Acute admission |  |
| **EXCLUSION CRITERIA** |  |
| Contraindications to haloperidol |  |
| Habitual antipsychotics |  |
| Antipsychotics in ICU before inclusion |  |
| Permanently incompetent |  |
| Delirium assessment non-applicable |  |
| Withdrawn therapy/brain death |  |
| hCG test |  |
| Consent unobtainable  |  |
| Admitted under coercive measures |  |
| Alcohol-induced delirium  |  |

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| **Data** | **Primary data source** |
| **STRATIFICATION VARIABLES** |  |
| Name/initials |  |
| Delirium motor subtype |  |
| Site | eCRF |
| Randomisation | eCRF |
| Time of randomisation | eCRF |
| **BASELINE FORM** |  |
| **GENERAL PATIENT INFORMATION** |  |
| Sex |  |
| Date and time of admission |  |
| Surgery  |  |
| **Co-morbidities** |  |
| Cancer  |  |
| **Risk factors** |  |
| Traumatic brain injury and stroke within 6 months |  |
| Mental or neurodegenerative illness |  |
| Haloperidol in hospital before ICU admission |  |
| Smoking, alcohol and substance abuse |  |
| Benzodiazepines |  |
|  |  |
| **SMS-ICU** |  |
| Systolic blood pressure |  |
| Vasopressors |  |
| Respiratory support |  |
| Renal replacement therapy |  |
| **DAY FORM** |  |
| **Time span** |  |
| Date/time | eCRF |
| **General assessment** |  |
| Mechanical ventilation |  |
| Coma  |  |
| **Delirium assessment** |  |
| Delirium, coma and subtype |  |
| **Delirium treatment** |  |
| Trial medication delivery and doses |  |
| Pausing criteria |  |
| Unexplained coma |  |
| Escape medication |  |
| Open-label haloperidol |  |
| Anti-psychotics |  |
| Restrain |  |
| **SAR** |  |
| Anaphylactic reaction |  |
| Agranulocytosis |  |
| Pancytopenia |  |
| Acute hepatic failure |  |
| Ventricular arrhythmia |  |
| Extrapyramidal symtoms |  |
| Tardive dyskinesia |  |
| Malignant neuroleptic syndrome |  |
| **DISCHARGE AND READMISSION FORM** |  |
| Date/time | eCRF |
| Discharged to |  |
| Date/time of possible readmission |  |
| **WITHDRAWAL FORM** |  |
| Date/time | eCRF |
| SAR/SUSAR |  |
| QT prolongation |  |
| Consent not given/further data registration |  |
| Coercive measures |  |
| Decision of treating clinician |  |
| **90 DAYS FOLLOW-UP** |  |
| Date | eCRF |
| If discharged from hospital within 90 days: Date of discharge and additional admissions |  |
| Dead |  |

Investigator (navn): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dato: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_ Underskrift: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**VEJLEDNING**

**Kildedokument**

Kildedatalisten anvendes af Good Clinical Practice (GCP) monitorerne til at validere indtastede data. Kildedokumentet er det første sted data registreres. Der skal angives en kilde til samtlige data, der indsamles i CRF’en og henvisningerne skal opføres i kildedatalisten. Hvis flere kilder er mulige, skal alle angives i prioriteret rækkefølge, dvs. kilder der vægter højest hvis data i de forskellige kilder ikke er identiske placeres først.

**Eksempler på kildedokumenter, som kan være både elektroniske og fysiske dokumenter**

EKG-udskrift, elektronisk medicin-journal, eCRF, epikrise, journalkontinuationer, sygeplejenotater osv.

Beskriv kildedokumentet så specifikt som muligt.

**Udarbejdelse og opbevaring**

Kildedatalisten skal foreligge underskrevet af lokal investigator ved initieringsbesøget. Det kan være nødvendigt at revidere listen undervejs i forsøget. Alle underskrevne versioner af listen, skal arkiveres i site master file.