**Primary data source**

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

**Department:**

**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| Withdrawn therapy/brain death |  |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  |  |

|  |  |
| --- | --- |
| **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 |
| **Sedcondary outcome measures** |  |
| 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 |  |
| 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 |
| 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 (name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Instructions**

**Data sources**

The primary data source list is used by the Good Clinical Practice (GCP) monitors in order to check that entered data are correct. The primary data source refers to the source/place where the data first appears (original data capture). Data sources must be listed for all data in the eCRF in the primary data source list above, prior to inclusion of the first patient. Data may have more than one data source. In this case all sources should be listed. The superior sources should be listed first in case the data differs between sources.

**Examples of sources from which data are captured - electronic or hard-copy documents**

Analysis print, ECG-print, electronic medical record, eCRF, nurse charts etc.

Describe the source as specific as possible.

**Completion and storage**

The Primary Data Source List must be signed by the local investigator before initiating the trial and filed in “Site Master File”. If the list is updated during the trial, please remember to place the new list in the Site Master File.