AID-ICU trial synopsis

Title	Agents Intervening against Delirium in the Intensive Care Unit randomized, stratified, parallel-grouped, blinded, placebo-controlled trial
Short title	The AID-ICU trial
Objectives	To assess the benefits and harms of haloperidol in patients with ICU-acquired delirium
Population	Acutely admitted adult ICU patients with delirium stratified at randomisation for site and type of delirium
Interventions	IV haloperidol regular and as needed as long as the patient has delirium
Comparator	IV placebo (saline)
Outcomes	**Primary** Days alive out of the hospital within 90 days post-randomisation **Secondary** 1. Number of days without delirium or coma in the ICU 2. Number of patients with one or more serious adverse reactions to haloperidol and number of serious adverse reactions per patient 3. Usage of escape medicine and dosage of escape medicine per patient 4. Number of days alive and off mechanical ventilation 5. 1-year mortality post-randomisation 6. EQ-5D-5L and EQ-VAS 1-year after randomization. Patients who have died will be assigned the lowest possible EQ-5D-5L and EQ-VAS score 7. Cognitive function 1-year after randomization as assessed by RBANS score at selected sites 8. A health economic analysis will be performed. The analytic details will be based on the result of the trial and specified (cost-effectiveness vs cost-minimisation analysis)
Eligibility	**Inclusion criteria** 1. Acute admission to ICU **AND** 2. Age ≥ 18 years **AND** 3. Diagnosed delirium with a validated screening tool as either CAM-ICU or ICDSC **Exclusion criteria** 1. Contraindications to haloperidol 2. Habitual treatment with any antipsychotic medication 3. Permanently incompetent (e.g. dementia, mental retardation) 4. Delirium assessment not applicable (coma or language barriers) 5. Withdrawal from active therapy or brain death 6. Fertile women with positive urine human chorionic gonadotropin (hCG) or plasma-hCG 7. Consent according to national regulations not obtainable 8. Patients under involuntary hospitalization by regulatory authorities 9. Patients with alcohol-induced delirium (delirium tremens)
Sample size	2 x 500 to power the study to assess a relative risk reduction or increase in the number of days alive and out of hospital at day 90
Trial Duration	The trial intervention will continue for a maximum of 90 days post-randomisation. Estimated recruitment period is 2 years commencing February 2018