Haloperidol prophylaxis in older emergency department patients.

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We hypothesize that addition of low-dose haloperidol prophylaxis (1.0mg twice-daily) on top of the existing standard of care reduces in-hospital delirium incidence, severity and duration in a general patient population, age 70 years or over, who are...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21334

Bron
NTR

Verkorte titel
HARPOON

Aandoening

Delirium

Ondersteuning

Primaire sponsor: VU Univeristy Medical Center Amsterdam
Overige ondersteuning: VU Univeristy Medical Center Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The incidence (percentage, %) and duration (days) of in-hospital delirium in both study arms (haloperidol and placebo group).

Toelichting onderzoek

Achtergrond van het onderzoek

Delirium is a severe neuropsychiatric disorder occurring frequently in the acutely admitted, older patient. Hospital prevalence numbers range from 8.6% to 52% in patients aged 65 years or over. Older patients who develop delirium are at risk of developing a range of negative outcomes such as increased hospital length of stay (LOS), high morbidity and mortality, cognitive and functional decline and increased institutionalisation after hospital discharge. As a result of these (long-term) negative health outcomes, delirium is associated with increased (non-) healthcare costs. Due to expected increase in the elderly population, this will be an even more significant health-problem in the near future. What causes delirium is usually multi-factorial, which makes delirium management very difficult. In order to prevent delirium, intervention strategies targeting reversible risk factors have been developed. Implementing these measures reduces the incidence of delirium, but not the delirium severity and duration. There may to be a promising role for prophylactic use of a low dose (≤ 2.0mg/24 hours) of the typical antipsychotic drug haloperidol: currently the drug-of-choice in the treatment of delirium once it develops. In selected patients undergoing (elective) hip surgery, prophylactic treatment with low-dose haloperidol (1.5 ¨C 2.0mg/24 hours) in older at-risk patients seems to reduce severity and duration of delirium, though its effect on delirium incidence is non-significant. However, these results are hardly generalizable due to study population and study-size. Further research on the effectiveness of additive early haloperidol prophylaxis in the prevention of delirium in acutely admitted older patients is needed. Given its multifactorial origin and the fact that haloperidol is still the drug of choice in the symptomatic treatment of delirium, consistent with current guidelines though evidence is lacking, we propose a double-blind, randomized, placebo controlled trial to evaluate the efficacy of prophylactic low-dose haloperidol (1.0mg twice-daily), rather than antipsychotics, benzodiazepines or melatonin, on delirium prevention in an older at-risk general patient population. The risk of developing delirium during hospital admission will be determined according to criteria mentioned in the Dutch ¡®Safety Management System (VMS) (www.vmszorg.nl).

Doel van het onderzoek

We hypothesize that addition of low-dose haloperidol prophylaxis (1.0mg twice-daily) on top of the existing standard of care reduces in-hospital delirium incidence, severity and duration in a general patient population, age 70 years or over, who are acutely admitted to the hospital through the emergency department (ED) and who are at-risk for delirium on admission.

Onderzoeksopzet

1. Baseline;

2. 3 and 6 months after discharge.

Onderzoeksproduct en/of interventie

Each subject will be randomly assigned to prophylactic treatment with either haloperidol or placebo for 7 days, starting the day of hospital admission. Dosage schedule: 1 mg twice-daily at 12am and 8 pm.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients age 70 years or over;

2. First presentation in the ED in the last month;

3 The patient and/or proxy is able to provide informed consent;

4 The patients and/or proxy speaks either Dutch or English;

5 The patient is at-risk for delirium according to the Dutch VMS delirium risk-questions;

6 The patient is admitted to the acute admission facility (AOA), general internal medicine (including geriatric unit) or surgery/orthopaedics department.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients presenting in the ED with delirium according to the DSM-IV criteria;

2. Patients with clinically significant cardiac disorders:

A. QTc interval prolongation (QTc ≥ 500ms);

B. Recent acute myocardial infarction;

C. Uncompensated heart failure;

D. Acute coronary syndrome (ACS);

E. Arrhythmias treated with class IA and III antiarrhythmic medicinal products;

F. History of ventricular arrhythmia;

G. History of torsades de pointes;

H. Clinically significant bradycardia;

I. Second or third degree heart block;

J. Uncorrected hypokalaemia.

3. Patients with vascular dementia;

4. Patients with Lewy Body dementia;

5. Patients with Parkinson dementia;

6. Patients with (a history of) hypokinetic movement disorders;

7. Patients with (a history of) malignant neuroleptic syndrome;

8. Patients with (a history of) serotonergic syndrome;

9. Patients with (a history of) central anticholinergic syndrome;

10. Patients who will be admitted to the oncology ward;

11. Patients who are enrolled in other medical- or drug studies;

12. Patients using QT prolonging drugs and other drugs of which concomitant use with haloperidol is contraindicated;

13. Patients using antipsychotics;

14. Patients using intramuscular neuroleptic depot injections.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	07-11-2012
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3059
NTR-old	NTR3207
Ander register	Clinicaltrials.gov : ID474
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A