Acute cardiometabolic adverse effects during treatment with haloperidol in elderly patients

Published: 19-07-2013
Last updated: 24-04-2024

Primary objective 1. To examine the association between the use of haloperidol and the acute changes in fastening serum glucose and QT interval in elderly patients undergoing surgery. Secondary objectives 1.To examine the association between the use...

Ethical review	Not approved
Status	Will not start
Health condition type	Deliria (incl confusion)
Study type	Observational invasive

Summary

ID

NL-OMON38934

Source
ToetsingOnline

Brief title
CMH- study

Condition

- Deliria (incl confusion)

Synonym
adverse effect

Research involving
Human

Sponsors and support

Primary sponsor: Tergooiziekenhuizen Hilversum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiometabolic, Elderly, Haloperidol

Outcome measures

Primary outcome

a. Serum level of fastening glucose (mmol/l). b. QT interval measured by

(holter) ECG using Fridericia*s formula .

Secondary outcome

1. Serum level of triglycerides (mmol/l). 2. Closure time (sec), measured by

Platelet Functional Analyser (PFA-100). 3. Serum concentration haloperidol (µg/

L). 4. Daily defined dose, total antipsychotic exposure in haloperidol users.

5. Genetic polymorphisms at D2 receptor, serotonin 2c receptor,

methylenetetrahydrofolate reductase (MTHFR), NUBPL and NOS1AP genes.

Study description

Background summary

It is difficult to extrapolate results of studies investigating metabolic adverse effects of antipsychotic drugs in the younger population to the elderly population, because of possible differences in indication for treatment, comorbidity and polypharmacy. Elderly are more sensitive to antipsychotic drugs through age related changes in peripheral and central pharmacokinetics and pharmacodynamics, resulting in different dose regimes. And age- associated changes in body composition, increased fat mass and decreased muscle mass enhance insulin resistance, which is related to an increased prevalence of metabolic syndrome in the elderly. Not all patients experience antipsychotic induced metabolic effects to the same extent. Available literature on antipsychotic induced cardiometabolic effects in elderly people is scarce, awareness of possible metabolic adverse effects in elderly is lacking in daily clinical practice and it is unclear if more effort is needed to improve monitoring of cardiometabolic risk factors in elderly patients. The aim of this study is to extend our knowledge of the acute cardiometabolic adverse effects of haloperidol treatment in elderly patients, focussing on changes in fastening

serum glucose and QT interval.

Study objective

Primary objective 1. To examine the association between the use of haloperidol and the acute changes in fastening serum glucose and QT interval in elderly patients undergoing surgery. Secondary objectives 1.To examine the association between the use of haloperidol and acute changes in triglycerides in elderly patients undergoing surgery. 2.To examine the association between the use of haloperidol and acute changes in platelet aggregation in elderly patients undergoing surgery. 3.To analyse the relation between dosage and concentration of haloperidol and changes in fastening serum glucose and QT interval in elderly patients. 4.To evaluate differences in DNA profile in patients with and without changes in fastening serum glucose and QT interval using haloperidol.

Study design

Prospective, observational study to examine acute changes in cardiometabolic parameters and platelet aggregation in elderly patients using haloperidol compared to elderly without using haloperidol.

Study burden and risks

This observational study has negligible risks and a minimal impact for participating patients. Integration of regular blood sampling and blood sampling for study purposes will be attempted.

Contacts

Public
Tergooiziekenhuizen Hilversum

Van Riebeeckweg 212
Hilversum 1213 XZ
NL
Scientific
Tergooiziekenhuizen Hilversum

Van Riebeeckweg 212
Hilversum 1213 XZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 70 years or older.
Admitted for a hip fracture or other fall- related fracture on the department of Surgery or Orthopaedics.
Inclusion within 24 hours after admission on the department.
The patient or representative speaks either Dutch or English.
Patient or representative must be able to give informed consent

Exclusion criteria

Use of an antipsychotic agent within 90 days before hospital admission.
Patient is not undergoing surgery for the hip fracture or other fall- related fracture.
Start or dose changes in the following medication in the 14 days before admission:
Thrombocyte aggregation inhibitors
QT- prolongating drugs
Antidiabetic drugs
Antihypertensive drugs
Cholesterol- lowering drugs
Additional for recording a holter electrocardiogram (ECG) for patients in subgroup 1:
History of pacemaker implantation, atrial fibrillation, bundle branch block, congenital QT-syndrome.
Use of QT prolongating drugs (CERT list 1 www.azcert.org) in the 14 days before admission.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Not approved

Date:	19-07-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	na goedkeuring METC zal aanmelding plaatsvinden.

Register	ID
CCMO	NL44683.041.13