Acute cardiometabole risico’s tijdens de behandeling met haloperidol bij ouderen.

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21267

Source
NTR

Brief title
CMH- study

Health condition

ouderen, delier, antipsychotica
elderly, delirium, antipsychotics

Sponsors and support

Primary sponsor: Tergooiziekenhuizen
Source(s) of monetary or material Support: Tergooiziekenhuizen

Intervention

Outcome measures

Primary outcome

1. QTc- prolongation measured with holter ECG;

2. Serum NT-proBNP, glucose, triglycerides;

3. Closure time.

Secondary outcome

1. QTc- prolongation measured with ECG;

2. Serum concentration haloperidol;

3. DDD;

4. Total antipsychotic expose;

5. DNA profile.

Study description

Background summary

Extrapolation of results investigating cardiometabolic side effects during antipsychotic use in the younger schizophrenic population to the elderly is difficult. This observational, prospective study is designed to extend our knowledge of acute cardiometabolic side effects during treatment with haloperidol in the elderly.
Therefore we will include patients 70 years and older admitted on the department of Orthopaedics or Surgery in Tergooiziekenhuizen with hip fractures or other fall-related fractures. The cardiometabolic function in patients treated with haloperidol for a delirium will be compared with cardiometabolic function of patients without treatment with haloperidol.

25-Apr-2013: METC-approval not received, trial will not be started.

Study objective

Antipsychotics (haloperidol) can cause acute changes in cardiovascular functions, metobolic parameters and platelet aggregation in elderly patients.

Study design

1. Holter ECG: Day 3 after initiation of haloperidol;

2. ECG, serum NT-proBNP, triglycerides and closure time: Baseline and day 3-5-7;

3. Glucose: Baseline, day 0-7 (daily check);

4. Serum concentration haloperidol: Day 4 after initiation of haloperidol;

5. DNA profile: Baseline.

Intervention

N/A

Contacts

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-
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Eligibility criteria

Inclusion criteria

1. Age 70 years and older admitted for hip fracture or other fall-related fractures;

2. Inclusion within 72 hours after admission;

3. 90 days of medication history available.

Exclusion criteria

1. Use of an antipsychotic agent within 90 days before admission;

2. Start or dose change in of any anticoagulants, Qtc prolongation drugs, antidiabetic drugs, antihypertensive drugs or cholesterol lowering drugs;

3. Terminal illness.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-12-2012
Enrollment:	128
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3517
NTR-old	NTR3679
Other	METC UMCU : 12-443
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A