Prevention of delirium in acute stroke

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To evaluate whether preventive treament with haloperidol lowers the risk for delirium in stroke patients with an increased risk for delirium.

Ethical review	Not approved
Status	Will not start
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON35482

Source
ToetsingOnline

Brief title
PODIAS

Condition

- Central nervous system vascular disorders
- Deliria (incl confusion)

Synonym
confusion; mental confusion

Research involving
Human

Sponsors and support

Primary sponsor: Kennemer Gasthuis
Source(s) of monetary or material Support: Uit eigen financiering. Subsidie bij Posthumus Meijes fonds is aangevraagd. Dit is een lokaal fonds van het Kennmer Gasthuis voor onderzoek vanuit het Kennmer Gasthuis

Intervention

Keyword: derlirum stroke prevention halperidol

Outcome measures

Primary outcome

occurence of delirium

Secondary outcome

Duration of delirium

Severity of delirium

Duration of admission

Score on Modified Rankin Scale at discharge

Discharge place (home, rehabilitation center, nursing home)

Mortality and morbidity at discharge, and six weeks and one year after

discharge

Study description

Background summary

Delirium is a common complication in hospitalized patients. The estimated incidence of delirium in stroke patients is 13-48%. Delirium is associated with increased morbidity, mortality and a longer duration of hospitalization. There are no prospective studies on preventive treatment with haloperidol in stroke patients.

The current study is a placebo controlled dubbelblinded randomized trial on preventive treatment with haloperidol in stroke patients with an increased risk for delirium. Patients admitted with an acute stroke are eligible for this study. The risk for delirium will be estimated based on several predisposing factors for delirium (age>75 years, co-morbidity, preexistent cognitive decline, visual or auditory problems, ADL-depency).
Treatment consists of haloperidol 1 mg three times daily for three days. If a delirium occurs during the first three days of admission the study is ended and

the patient will be treated according to the current guidelines for delirum. Participants will be asked to complete several questionnaires on admission and the following 4 days. Several questionnaires are already standard in stroke patients admitted to a stroke unit.
The tests are: DSM-IV criteria for delirum, Confusion Assessment Method (CAM), Confusion Assessment Method for the ICU (CAM-ICU), Delirium Rating Scale (DRS), IQCODE-N, Groningen Frailty Indicator, Mini Mental State Examinations (MMSE), Delirium Observation Screening (DOS), Delier-O-meter (DOM), NIHSS score, Oxfordshire Community Stroke Project (OCSP) criteria, Barthel Index en Modified Rankin Scale. Most scales are filled in at admission (extra time for patient 15 minutes). The first four days of admission the following scales will be filled in: CAM, CAM-ICU, DOS en DOM; DRS en DSM-IV criteria if a delirum is present (extra time 5 minutes per day).

On admission routine laboratory investigations are performed in all patients. At this routine laboratory examination and at day two 10 ml EDTA blood will be drawn and stored anomised for analyses of cytokine profiles. During the first for days the patient will wear an actimeter (sort of watch) at the non-dominant wrist to register movement activity.

Stroke patients are routinely revised 6 weeks after discharge. At this visit the MMSE, CAM, CAM-ICU and DRS will be filled in(10 minutes). If consent is given an extra visit is planned one year after discharge to repeat these measures (10 minutes).

Study objective

To evaluate whether preventive treament with haloperidol lowers the risk for delirium in stroke patients with an increased risk for delirium.

Study design

Placebo controlled dubbelblinded trial

Intervention

Haloperidol 1 mg 3 times daily for three days.

Study burden and risks

The nature and extent of the burden and risks associated with participation is low.
The potential benifit of participation is high.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with (suspected) stroke
- no delirium on admission (DRS<12; CAM < 2+1)
- expected duration of hospitalisation >48 hours
- Score on deliersticker * 5
- Time between admission and estimation of risk score and DRS/CAM < 24 hours

Exclusion criteria

- Score deliersticker < 5
- delirium on admission (DRS> 12; CAM * 2+1; CAM-ICU * 2 + 1)
- not able to perform delirum screening (DRS, CAM, CAM-ICU) on admission

- expected duriong of hospitalisation < 48 uur
- contraindication for use of haloperidol: history of allergy for haloperidol, severe liverinsufficiency, Parkinson's disease, Lewy body dementia, parkinsonism, epilepsy, use of levodopa/dopamine agonist, use of antipsychotics (e.g., haloperidol) or cholinesterase inhibitors
- Pronged Qt interval: Qt interval on EKG on admission * 500ms .
- Time between admission and estimation of risk score and DRS/CAM < 24 hours
- Participation in same study in the last three months
- severe impairment of consciousness (coma)
- not possible to obtain informed consent
- Patients, family of physician refuse to participate

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	300
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Haldol
Generic name:	haloperidol
Registration:	Yes - NL intended use

Ethics review

Not approved

Date:	12-07-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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
EudraCT	EUCTR2009-015604-25-NL
CCMO	NL29469.094.09