Methylphenidate, rivastigmine or haloperidol in hypoactive delirious intensive care patients: a single centre, randomized, mono-blind pilot trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Interventional

Summary

ID

NL-OMON31220

Source
ToetsingOnline

Brief title
Methylphenidate, rivastigmine or haloperidol in hypoactive ICU-delirium

Condition

- Deliria (incl confusion)

Synonym
ICU-psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Delirium, Intensive Care Unit, Methylphenidate, Rivastigmine

Outcome measures

Primary outcome

- the feasibility of a large randomized, placebo controlled, dubbleblind clinical trial to investigate the use of methylfenidate, rivastigmine or haloperidol in hypoactive ICU-delirium.

Secondary outcome

- Does the treatment with methylphenidate, rivastigmine or haloperidol shorten the duration of hypoactive ICU-delirium in comparison to no intervention?
- Does the treatment with methylphenidate or rivastigmine shorten the duration of hypoactive ICU-delirium in comparison to intervention with haloperidol or no intervention?
- Does the treatment with methylphenidate or rivastigmine decrease the severity of hypoactive ICU-delirium in comparison to intervention with haloperidol or no intervention?
- Does the treatment with methylphenidate or rivastigmine shorten the hospital or ICU stay in comparison to the intervention with haloperidol or no intervention?
- Does the treatment with methylphenidate or rivastigmine decrease the amount of rescue medication used in comparison to the treatment with haloperidol or no intervention?
- What is the frequency of the side effects of methylphenidate, rivastigmine

and haloperidol?

Study description

Background summary

Delirium is characterized as: (1) Disturbance of consciousness (i.e., reduced clarity of awareness of the environment) with reduced ability to focus, sustain, or shift attention. (2) A change in cognition or the development of a perceptual disturbance that is not better accounted for by a preexisting, established, or evolving dementia. (3) The disturbance develops over a short period of time (usually hours to days) and tends to fluctuate during the course of the day. (4) There is evidence from the history, physical examination, or laboratory findings that the disturbance is caused by the direct physiological consequences of a general medical condition. Delirium can be classified into three different subtypes: hyperactive, hypoactive and mixed type.
Delirium is frequent among ICU patients. ICU-delirium is not only associated with stress and discomfort of the patient and their relatives, but also with a worse prognosis. ICU-delirium is also associated with higher ICU and total hospital costs. According to international guidelines, the treatment severe aggitation in delirium is haloperidol. This trial will possibly identify new treatments for delirium.

Study objective

The purpose of this pilot-trial is the feasibility of a large randomized, placebo controlled, dubbleblind clinical trial to investigate the use of methylfenidate, rivastigmine or haloperidol in hypoactive ICU-delirium. Secondary we will try to compare the outcomes (duration of delirium, severity of delirium, length of ICU/hospital stay en side effects) between the different interventions.

Study design

single centre, randomized, placebo-controlled, mono-blind pilot trial

Intervention

Participants of this study will be randomised between for intervention groups:
- Methylphenidate 5 mg. 2 dd 1, oral, increased every day with 10 mg. until negative CAM(-ICU) or side-effects. Maximum dosage 30 mg./day
- Rivastigmine 1,5 mg. 2 dd 1, oral, increased every third day with 3 mg. until negative CAM(-ICU) or side-effects. Maximum dosage 12 mg./day
- Haloperidol 2,5 mg. 2 dd 1, oral. (if patient is 69 years or younger)

Haloperidol 1 mg. 2 dd 1, oral (if patient is 70 years or older)
- No intervention

Study burden and risks

Burden:
The participants will be screened twice a day by the investigator, using the CAM-ICU (duration: circa 5 minutes). This is a questionnaire and not an invasive method.
Risks
Rivastigmine and methylphenidate are not registered for the treatment of delirium, both drugs however are frequently used and extensively tested. Participants receiving either methylphenidate, rivastigmine or no intervention will be deprived of the treatment as recommended by international guidelines (haloperidol). In current practice however haloperidol is only given in case of severe agitation, and especially hypoactive delirious patients will receive no therapy at all.

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

Older than 18 years.
Diagnosed as hypoactive delirium

Exclusion criteria

Pregnancy; epilepsy; M. Parkinson; Lewy-body dementia; prolonged QT-time; known allergie to the medicinals used; renal replacement therapy; hepatic encephalopathy; hypertheroid; glaucoma; previous suicide attempts; syndrome of Gilles de la Tourette; patients which cannot receive the medication oraly or through a nasogastric tube.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2008
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Haloperidol
Generic name:	Haldol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Methylphenidate
Generic name:	Ritalin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Rivastigmine
Generic name:	Exelon
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	01-11-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-12-2007
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
EudraCT	EUCTR2007-003965-42-NL
CCMO	NL18202.041.07