Dexmedetomidine vs. clonidine in delirious intensive care patients: a randomised open-label trial

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Primary objective:the effects of sedation with clonidine or dexmedetomidine on the duration of haloperidol-resistent delirium in intensive care patientsSecondary objectives:the effect of treatment with clonidine or dexmedetomidine on1. total of...

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

Summary

ID

NL-OMON38662

Source
ToetsingOnline

Brief title
The effect of dexmedetomidine and clonidine on delirium

Condition

- Deliria (incl confusion)

Synonym
confusion, Delirium

Research involving
Human

Sponsors and support

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

Intervention

Keyword: alpha2-agonist, Clonidine, Delirium, Dexmedetomidine

Outcome measures

Primary outcome

Duration of treatment with the alpha2-agonist in days (intervals of 6 hours)

untill the first negative CAM-ICU score of the three following days with a

negative CAM-ICU score

Secondary outcome

- RASS score while treated with the alpha2-agonist

- total number of days till extubation after start alpha2-agonist (in case the

patients are mechanical ventilated)

- total number of days till discharge intensive care unit

- total of 'delirium-free' days (intervals of 6 hours)

- total duration of the delirium episode (intervals of 6 hours) (end of

delirium defined as three successive days of negative CAM-ICU scores)

Study description

Background summary

Delirium is a common psychiatric syndrome in Intensive Care Units. It is an independent predictor of longer hospital stay, higher hospital costs and people with delirium show an threefold increase in mortality rate. It is associated wit longterm cognitive impairment, impaired activity of daily living and decreased quality of life. For all this reasons, a good treatment for delirium is indicated. Worldwide, the most used medicine for treatment of delirium is haloperidol (Haldol). For patients with a (severe) delirium, haloperidol is not as effective or not enough to suppress the symptoms of a delirium. In these cases, other medications for treatment are indicated. Alpha2-agonists like clonidine and dexmedetomidine, are medications used in clinical practice,

especially for delirium with sympathetic over activity. Trials involving clonidine and dexmedetomidine have reported a lower incidence of delirium and shorter time to extubation. The choice of which alpha2-agonist is given to a patient with delirium, is mainly based on the experience and personal preference of the attending physician.
Clonidine is an alpha2-agonist that, based upon extended clinical experience, is used 'off-label' for sedation of IC-patients. Dexmedetomidine is licensed in the Netherlands since 2011 for sedation of intensive care patients. It is a more selective alpha2-agonist then clonidine and is a much more expensive treatment, cause it's still a patent medicine. A study to compare these two alpha2-agonists has not been performed so far, nor are there any clinical clues which of these two has a better effect on delirious patients.

Study objective

Primary objective:
the effects of sedation with clonidine or dexmedetomidine on the duration of haloperidol-resistent delirium in intensive care patients

Secondary objectives:
the effect of treatment with clonidine or dexmedetomidine on
1. total of 'delirium-free days'
2. the duration till extubation in case patients are mechanical ventilated
3. the duration till reaching the aiming level of sedation (RASS0)
4. the duration till discharge of the ICU

Study design

The subject is an exploratory study. We conducted a randomized, single centre pilot trial in the intensive care unit at the Isala klinieken, Zwolle, The Netherlands. Duration of the study is 12 weeks.We want to include 24 patients.

Intervention

At the moment when treatment with an alpha2-agonist is indicated on medical conditions, patients are randomized into the clonidine-group or into the dexmedetomidine group. At that moment intervention take place.

Medication will be given intravenous in the following dose:
Clonidine: bolus of0,5 ug/kg followed by maintenance dose of minimal 0,5 ug/kg/hr - maximum 1,5 ug/kg/hr
Dexmedetomidine: loadingdose of 0,7 ug/kg/hr, maintenance dose of minimal 0,2 ug/kg/hr - maximum 1,4 ug/kg/hr.

Study burden and risks

The burden and risks associated with participation is similar with persons not involved in this study / in the clinical setting. When the use of an alpha2-agonist is indicated for medical reasons, patients get clonidine or dexmedetomidine. The choice which, is mainly depended on preference and experience with the medication of the attending physician at that moment. The only difference in this study with the clinical setting is, that the choice of alpha2-agonist is made randomization. Patients will get the same critical care treatment as when they wish not to participate in this study. There will be no extra interventions in this study.

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

- age > 18

- no response on treatment with haloperidol (max. dose till 3x5mg)
- positive score CAM-ICU

Exclusion criteria

- history of epilepsy, Parkinson's disease, hypokinetic rigid syndrome, or Lewy body dementia
- treatment with antipsychotic drugs
- pregnancy or breastfeeding
- CVA < 6months
- hypotension (< 90mmHg)
- bradycardia (<50/min)
- MAP < 60mmHg
- comatose patients (RASS -4 or -5)
- recent myocardial infarction of severe coronal insufficiency
- 2nd of 3rd degree AV-block or sicksinussyndrome
- known allergic reaction on clonidine of dexmedetomidine

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2013
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dexdor
Generic name:	Dexmedetomidine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Duraclon
Generic name:	Clonidine hydrochlorid, solution for injection
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	17-09-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	15-10-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2013-003547-39-NL
CCMO	NL46077.075.13