Causes and outcomes of delirium in patients aged 65 and older in relation to biochemical parameters

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To study the relationship between (a) abnormal concentrations of plasma amino-acids, pterins, HVA and inflammatory parameters and (b) the severity, duration and outcome of delirium. To find a biochemical profile that predicts the occurrence of a...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON36917

Source
ToetsingOnline

Brief title
DITO Study (delirium in the old)

Condition

- Ancillary infectious topics
- Deliria (incl confusion)
- Bone and joint therapeutic procedures

Synonym
acute confusion

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W,Vereniging Trustfonds Erasmus Universiteit Rotterdam

Intervention

Keyword: causes, delirium, older persons, outcomes

Outcome measures

Primary outcome

Primary: The severity and clinical outcome of the delirium in relation to the

biochemical parameters. The end of delirium is defined as the resolution of

delirium symptoms on the DOS scale.

Secondary outcome

Secundary:

1 DRS-R-98 scale (severity delirium) and MMSE score at the assessment moments.

2 The concentration of HVA and neopterin in plasma.

3 The concentration of interleukine-6 and CRP in the serum.

Study description

Background summary

Delirium is a complex neuropsychiatric syndrome with an acute onset and fluctuating course. Prevalence figures for medical inpatients range from 10-60%. Older patients with a delirium are at significant risk of complications, prolonged hospital admission, institutionalisation and death. Treatment is based on treating the underlying cause -usually a chest or urinary tract infection-. Treatment of the neuropsychiatric symptoms is symptomatic, and consists of antipsychotics and benzodiazepines.

Several studies have suggested the presence of disturbed cholinergic, dopaminergic and serotonergic pathways in delirium. Especially, a disturbed metabolism of the amino-acid tryptophan has been found, as well as an increase

in the metabolite of dopamine, homovanillic acid (HVA). Evidence exists that a cytokine response is present, especially of interleukin (IL)-6. Also, there is an increase in C-reactive protein [CRP] and in the oxidative stress marker neopterin.

Despite an increased awareness of the importance of the early recognition and treatment of delirium, figures for complete recovery are poor. Mortality is high and many patients do not return to their previous level of functioning.

Our hypothesis is that the levels of neopterin, HVA, and inflammatory parameters can be of prognostic value in the diagnosis, treatment and outcome of delirium. The current study is proposed to investigate this issue.

Study objective

To study the relationship between (a) abnormal concentrations of plasma amino-acids, pterins, HVA and inflammatory parameters and (b) the severity, duration and outcome of delirium. To find a biochemical profile that predicts the occurrence of a delirium during the stay in the rehabilitation ward.

Study design

An open controlled study in patients diagnosed with a delirium during or at admission to the rehabilitation wards. The diagnosis delirium is based on the DSM-IV criteria. Observation of delirium will be performed using the Delirium Observation Screening Scale (DOS-scale). To determine the severity of delirium a Delirium Rating Scale (DRS-R-98) will be used. Whether or not the delirium is caused by infection will be recorded. Every patient will undergo an MMSE and blood tests.

Study burden and risks

Two extra venous blood samples will need to be taken, these will be combined as much as possible with taking of blood samples for the regular treatment.

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 65 years or older
·Admitted to the rehabilitation ward of Verpleeghuis Laurens Antonius Binnenweg, Rotterdam.
·Diagnosis of delirium made at or during admission (DSM IV 293.0).
·Informed consent to participate in the study, signed by the patient or the legal representative.
-Consent tot participate can also be given at the end of the study (if consent is not given, the CRF will be deleted).

Exclusion criteria

·Diagnosed with a severe, instable medical condition other than the reason for admission
·Contra-indication for the use of haloperidol
·Known neuroleptic malignant syndrome
·Tardive dyskinesia
·Lewy-body dementia
·Ongoing treatment with an antipsychotic other than haloperidol
·Severe dementia defined as an MMSE-score of <11/30 points in patients without a delirium at inclusion
·Unable to speak and/or understand dutch
·Admission shorter than 5 days

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-05-2010
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	10-08-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-12-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	01-02-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL18154.078.07