Screening for delirium in the Intensive Care Unit: a comparison study

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

Summary

ID

NL-OMON30770

Source
ToetsingOnline

Brief title
screeningsinstruments for delirium IC

Condition

- Deliria (incl confusion)

Synonym
acute confusion, delirium

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 Units, screeninginstruments

Outcome measures

Primary outcome

Primary study parameters are the diagnostic value of both screening instruments (sensitivity, specificity and predictive value) as compared to the gold standard, the DSM-IV criteria.

Secondary outcome

Secundary outcome parameters are the value of the impression of the ICU physician (sensitivity, specificity and predictive value) as compared to the gold standard, the DSM-IV criteria.

Study description

Background summary

Delirium in Intensive Care Unit (ICU) patients often goes unrecognized. Delirium has serious consequences including increased length of stay and worse outcome and can be treated. Different screening instruments are developed for ICU nurses. Using different tools, the reported incidence of delirium during ICU stay varies between 16 and 83%. It is uncertain whether the incidence varies because of differences in case-mix or because of differences in diagnostic value of the screening instruments. The Confussion Assessment Method for the Intensive Care (CAM-ICU) and the Intensive Care Delirium Screening Checklist (ICDSC) are mostly used in the ICU. These instruments have never been tested within the same population.

Study objective

The primary objective of this study is to test both the CAM-ICU and the ICSDS, using the DSM-IV criteria for delirium as golden standard. A secundary objective is to assess the value of the impression of the ICU physican whether or not a patient is delirious.

Study design

In this study, two screening instruments for delirium in ICU patients (CAM-ICU and ICDSC) will be compared with a gold standard, a neuropsychiatric assessment by a neurologist, psychiatrist or clinical geriatrician, using DSM-IV criteria for delirium. In addition, the impression by the physcian will be compared with the same gold standard.

Study burden and risks

There are no risks associated with screening for delirium; the burden is minimal

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

ICU-patients of the Univerity Medical Centre

Exclusion criteria

Patient who are deeply sedated (Ramsayscore 5 or 6)
Comatose patients (Glasgow Coma Score less than 8)
Patients who receive sedatives between evaluations with the various instruments

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-03-2007
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
CCMO	NL16002.041.07