Delirium in elderly patients: risk factors and outcomes

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The main aims of the proposed study were (1) to determine the effect of delirium on cognitive-, psychological-, functional-, and health outcomes at discharge, 3, 6 and 12 month follow-up. Patients with a delirium at admission will be compared with...

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

Summary

ID

NL-OMON33027

Source
ToetsingOnline

Brief title
Delirium: risk factors and outcomes

Condition

- Deliria (incl confusion)

Synonym
confusion, Delirium

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognition, Delirium, Psychological functioning, Riskfactors

Outcome measures

Primary outcome

Primary: Cognitive and psychological functioning over time.

Secondary outcome

Secondary: All-cause mortality, morbidity.

Study description

Background summary

Delirium is one of the most common neuropsychiatric complications in older patients admitted to the hospital. Few studies have examined how cognition and psychological factors develop over time after a delirious episode. Furthermore, there is only a paucity of studies that have taken into account different onsets and subtypes of delirium. In order to develop interventions, however, it is important to have a clear view of (a) effects of delirium on cogntive and psychological fucntioning and different health outcomes and (b) factors that influence cognitive and psychological functioning after delirium.

Study objective

The main aims of the proposed study were (1) to determine the effect of delirium on cognitive-, psychological-, functional-, and health outcomes at discharge, 3, 6 and 12 month follow-up. Patients with a delirium at admission will be compared with those who develop one in hospital. Within these two groups, the three delirium subtypes will be differentiated. The delirious patient groups will also be compared with an age-matched control group; (2) to identify factors that may influence psychological and cognitive functioning and health outcomes in (a) elderly patients with delirium at hospital admission and (b) those who develop delirium during their hospital stay, and to determine whether there are any differences between these risk factors for the three delirium subtypes.

Study design

A longitudinal and cross-sectional design will examine the effect of delirium

on a variety of outcomes.

Study burden and risks

Burden: At discharge and at follow up patients will participate in cognitive tests and fill out questionnaires. This will take approximately 2 hours each time, including breaks. Assessing cognitive functioning with the MMSE and sometimes with the CAMCOG is standard clinical care in the TweeSteden hospital, but adding questionnaires to this procedure is not. During follow-up, patients* assessment will take place after a control-appointment by the geriatric physician.
Risks: In our opinion, there are no risks associated with participation. The principal investigator, project leader or geriatric physician can decide to exclude a patient from the study for urgent medical reasons.

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

Inclusion criteria patient group: All patients who are admitted to the Department of Geriatrics with a delirium or who develop a delirium during their hospital stay, will be asked for participation in the proposed study when their delirium has ended.
Inclusion criteria control group: All patients who are acutely admitted (within 3 days) to the Department of Geriatrics and did not developed a delirium during their hospital stay.

Exclusion criteria

Exclusion criteria:
(1) A delirium at time of assessment
(2) A Mini-Mental State Exam score below 18, indicating severe cognitive problems
(3) Patients not capable of giving informed consent
(4) Sight and/or hearing impairments
(5) A palliative policy
(6) Inability to speak, read, write or understand Dutch
(7) Patients who are not testable according to physicians/nurses

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-02-2009
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	19-02-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-02-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL26507.028.08