Post-delirium Cognitive Impairment * PET and Neuropsychological Characteristics

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To assess in vivo microglial activation (as a validated marker of neuroinflammation) using PET-CT and associated neuropsychological characteristics in patients recovered from sepsis associated delirium.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Observational invasive

Summary

ID

NL-OMON36224

Source
ToetsingOnline

Brief title
PodeCI

Condition

- Central nervous system infections and inflammations
- Deliria (incl confusion)

Synonym
Delirium, dementie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZON-MW

Intervention

Keyword: Cognitive impairment, Neuropsychology, PET-CT, Post-delirium

Outcome measures

Primary outcome

1) Cerebral PK11195 binding potential (BP).

2) Test-score on different neuropsychological domains.

Secondary outcome

1) Duration of delirium.

2) DRS-R-98.

3) MMSE.

Study description

Background summary

Delirium is a highly frequent complication developing in a wide array of medical conditions. In critically-ill elderly patients admitted to the ICU, estimations of occurrence rates are as high as 80%. The long-term health consequences associated with delirium are becoming increasingly appreciated in recent years. Meta-analysis has shown a significantly higher risk of dementia, institutionalization and death in the years following delirium. Although research in post-delirium patients is scarce, various findings suggest the pathophysiological importance of prolonged neuroinflammation due to cholinergic deficiency.

Study objective

To assess in vivo microglial activation (as a validated marker of neuroinflammation) using PET-CT and associated neuropsychological characteristics in patients recovered from sepsis associated delirium.

Study design

Observational, cross-sectional, case-control study.

Study burden and risks

The only risk related to participating in this study for both cases and controls is that MRI might reveal unexpected findings. Whenever this would occur, patients will be informed by one of the principle investigators and will be offered consultation at the outpatient clinic of the Department of Neurology of the AMC. No further risks are related to the other procedures, including PET-CT imaging. Effective dose equivalents are specified in the *Radiation burden*-form, which will be separately admitted for approval to the Department of Radiology.
The only extra burden related to participating in this study is that patients have to travel to the AMC and VUmc after discharge to undergo MRI, PET-CT and neuropsychological evaluation. Completion of the studyprocedures is estimate to take 6 hours in total.

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

Cases/controls: 1) age >65 jaar
Cases: 2) Clinical diagnosis of delirium during hospital admission, 3) Development of sepsis <14 days prior to delirium, 4) Clinical recovery from delirium at discharge.

Exclusion criteria

1) Diagnosis of dementia or other major central nervous system pathology or psychiatric disease; 2) Previous episode of delirium; 3) Indication of prior cognitive impairment; 4) History of alcohol/substance abuse or severe headtrauma.
Cases: 5) Physical disability at discharge necessitating discharge to a nursing facility

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:	Recruitment stopped
Start date (anticipated):	06-12-2011
Enrollment:	74
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL37129.018.11

Study results

Date completed:	13-05-2013
Actual enrolment:	1

Summary results
Trial ended prematurely