Prevalence of hiv-associated neurocognitive disorders (HAND).

Published: 22-11-2011
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The aim of the study is to explore the prevalence of HAND in people living with hiv.

Ethical review	Not approved
Status	Will not start
Health condition type	Ancillary infectious topics
Study type	Observational non invasive

Summary

ID

NL-OMON35476

Source
ToetsingOnline

Brief title
hiv-associated neurocognitive disorders

Condition

- Ancillary infectious topics
- Cognitive and attention disorders and disturbances

Synonym
cerebral dysfunction, hiv-associated neurocognitive disorder

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: HAND, hiv, Neurocognitive

Outcome measures

Primary outcome

Is the prevalence of a positive HAND screening test-outcome with the hiv dementia scale (less than 14 points is a positive outcome), higher in people living with hiv, compared to people living with diabetes mellitus tye 2 or healthy volunteers?

Secondary outcome

Can we identify determinants associated with a positive result on the hiv dementia scale?

Study description

Background summary

HIV can cause various neurocognitive complications, in the literature described as hiv-associated neurocognitive disorders (HAND). In the beginning of the aids-epidemic, HAND was an often seen problem, presented as the aids-dementia-complex. Since the introduction of the combination Antiretroviral Therapy (cART) the situation has changed, and aids dementia complex is now seldom seen in treated patients. However, the prevalence of mild neurocognitive disorders is still present at a high level. There are even indications that in patients with an undetectable viral load and a good immunological status, the neurologic damage continues to increase. Because the possible enormous impact of HAND on the quality of life, adherence and mortality, it is important to detect/diagnose HAND in an early stage to prevent further damage and, if possible, to diminish the complains or consequences. Patients themselves are increasingly worried about neurocognitive problems leading to more attention for this topic during outpatient visits. In October 2011, the renewed European Aids Clinical Society Guidelines were published in which routinely screening for HAND is advised. However, this advice is based on expert opinion and further evidence is urgently needed.

Study objective

The aim of the study is to explore the prevalence of HAND in people living with

hiv.

Study design

A qualitative exploration study with a cross-sectional, observational design.

Study burden and risks

A minimal burden without any risk for the patient.

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:
- diagnosis hiv
- 18 years or older
- capable of speaking and reading Dutch
- adequate sight and hearing ability to join the study;Inclusion criteria controlgroup Diabetes mellitus:
- diagnosis DM 2
- 18 years or older
- capable of speaking and reading Dutch
- adequate sight and hearing ability to join the study
- GFR>30;Inclusion criteria controlgroup healthy volunteer:
- 18 years or older
- capable of speaking and reading Dutch
- adequate sight and hearing ability to join the study

Exclusion criteria

Exclusion criteria:
- drugs- and/ or alcohol abuses (in the past two years)
- Diagnosis of depression (current or last year)
- current use of anti-depressive or anti-psychotic medication
- history of learning disabilities, dyslexia or mental retardation
- history of Cardiac Vascular Attack or neuro-syphilis with sustained brain damage
- Vascular diseases (cerebral, cardiac and peripheral)
- (pre)terminal kidney failure, defined as GFR <30
- Pregnancy;Exclusion criteria control group diabetes mellitus:
- drugs- and/ or alcohol abuses (in the past two years)
- Diagnosis of depression (current or last year)
- current use of anti-depressive or anti-psychotic medication
- history of learning disabilities, dyslexia or mental retardation
- history of Cardiac Vascular Attack or neuro-syphilis with sustained brain damage
- Vascular diseases (cerebral, cardiac and peripheral)
- (pre)terminal kidney failure, defined as GFR <30
- symptomatic hypoglycaemia in the past 3 days
- Pregnancy;Exclusion criteria control group of healthy volunteers:
- drugs- and/ or alcohol abuses (in the past two years)
- Diagnosis of depression (current or last year)
- current use of anti-depressive or anti-psychotic medication
- history of learning disabilities, dyslexia or mental retardation
- history of Cardiac Vascular Attack or neuro-syphilis with sustained brain damage
- Vascular diseases (cerebral, cardiac and peripheral)
- (pre)terminal kidney failure, defined as GFR <30
- Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	225
Type:	Anticipated

Ethics review

Not approved

Date:	22-11-2011
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	NL38483.041.11