The ART-NECO study;Long term effective combination antiretroviral therapy (cART) and its effect on neurocognition. A prospective cohort study to assess the feasibility of two short cognitive screen tests in patients infected with HIV1 and the development of neurocognitive impairment over time

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To examine neurocognition in 100 HIV1 seropositive patients on chronic effective cART using three different tests: the Montreal cognitive assessment (MoCA) , the International Aids Dementia scale (ADS) and extensive neuropsychological testing of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35825

Source
ToetsingOnline

Brief title
Art NeCo

Condition

- Viral infectious disorders
- Neurological disorders NEC

Synonym
Neuro-HIV

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Abbott,Farmaceutische Industrie

Intervention

Keyword: cART, HIV, Neurocognition, Neuro-HIV

Outcome measures

Primary outcome

- the incidence of cognitive deficits in a Dutch cohort of HIV1 seropositive

patients on chronic cART;

- the utility, the sensitivity and specificity of a short cognitive screening

test (the MoCA) in detecting HAND, and the International Aids Dementia scale in

comparison with extensive neuropsychological tests

Secondary outcome

- The course of cognitive function in HIV infection over one year

- the detection of brainabnormalities visualized by MRI

- to establish the relation between HIV-associated neurocognitive disorders

and quality of life, subjective well-being and subjective cognitive complaints.

Study description

Background summary

An increasing number of papers report on cognitive deficits in HIV seropositive

patients even during long-term successful treatment with combination antiretroviral therapy (cART).
Limited penetration of antiretroviral (ARV) drugs into the brain and ongoing viral replication followed by insidious damage of the brain is supposed to be a major factor for the development of neurocognitive impairment in HIV patients. Besides, many other factors like age, co infections, and comorbidities are supposed to be involved.
It can be expected that in future cognitive disfunction may occur more often in HIV1 seropositive patients, particularly with growing age.
The clinical significance of cognitive deficits however is not exactly known. Furthermore a short cognitive screening test for detection of cognitive deficits is highly warranted in clinical practice, as extensive neuropsychological tests are not attainable in this setting.
The international aids dementia scale (ADS) is recommended in literature to assess cognitive dysfunction. But this test is not appropriate for detection of mild-to moderate cognitive disorders. The Montreal Cognitive Assesment also can be used, but has not been investigated in HIV seropositive patients.
The present study proposal seeks to investigate the utility of and to compare the three different sets of cognitive function tests (i.e extensive neuropsychological assessment, the international Aids Dementia scale and the MoCa) in a Dutch cohort of HIV infected patients on chronic effective combination antiretroviral therapy. The second aim is to corellate cognitive impairment to structural brain abnormalities, visualized by MRI.

Study objective

To examine neurocognition in 100 HIV1 seropositive patients on chronic effective cART using three different tests: the Montreal cognitive assessment (MoCA) , the International Aids Dementia scale (ADS) and extensive neuropsychological testing of five domains.
- To establish the utility of MoCA and ADS as screening tests for cognitive function
- To determine the course of cognitive functioning over a 1-year period;
- To establish the relation between HIV-associated neurocognitive disorders and quality of life, subjective well-being and subjective cognitive complaints.
- To establish the incidence of structural brain abormalities on MRI

Study design

One hundred HIV 1 seropositive patients on chronic effective cART will be recruited for this study. After informed consent an extensive neuropsychological test (appendix 1) , the ADS (appendix 2) and the MoCA (appendix 3) will be performed. A depression scale and a questionnaire on quality of life and a MRI of the brain will be done as well. The neuropsychological examination will include the following domains: memory, attention and concentration, executive functioning, motor function, processing

speed and visual construction.

Furthermore, an MRI of the brain will be made

The neuropsychological assessments will be repeated after one year. Slight modifications will be brought into the test batteries in order to prevent a learning effect. The reliable change index (RCI) will be calculated as a correction for a potential learning effect. Symptom validity and psychosocial variables will be taken into account.

Intervention

Neuropsychological test
MRI cerebrum
Lumbar puncture(s)
Blood punctures

Study burden and risks

2-3 extra hospital-visits

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

* HIV-seropositive 18-65 years (Western Blot)
* Treatment with cART
* HIVRNA in plasma < 50 copies/ml for one year

Exclusion criteria

* Active opportunistic infection
* Active psychiatric disorder for which treatment is indicated
* Overt cognitive disorder due to other co morbidity (e.g. of vascular origin)
* Malignancy
* Established neurosyphilis
* Drug addiction
* Excessive (> 2 U/d) use of alcohol

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:	Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	16-01-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-01-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL37277.091.11