A prospective explorative cross sectional clinical study to investigate the neurocognitive effects of human Immunodeficiency virus and the influence of highly active anti retroviral (HAART) therapy on CSF viral replication and biomarkers for neurodegeneration in HIV infected patients on chronic therapy with HAART

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1 To investigate the influence of HAART on CSF viral load, development of HIV resistance, neurotransmitters and biomarkers for neurodegeneration2 To explore the neurocognitive effects of HIV infection and its treatment3 To investigate the...

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

Summary

ID

NL-OMON33642

Source
ToetsingOnline

Brief title
Neurona-light

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: Ministerie van OC&W

Intervention

Keyword: CNS- effecs, HIV, HIV-treatment

Outcome measures

Primary outcome

HIVRNA in CSF

Drug levels, proteins and biomarkers for neurodegeneration in CSF

Secondary outcome

neuropsychological abnormalities

abnormalities in MRI of the brain

Study description

Background summary

Treatment with ART leads to partial recovery of immunity and delay of disease progression in the majority of HIV infected patients. However there are concerns that, despite effective suppression in peripheral blood, HIV replication continues in sanctuary sites. The central nervous system is one of the important sanctuary sites for HIV, and therefor HIV may have many neurological manifestations. Persistent viral replication in the CNS and

continuous exposure to viral protein may induce cerebral damage at long term. Limited penetration of antiretroviral drugs into the CNS is considered one of the main reasons for persistent viral replication. In this study it will be investigated whether the different HAART regimes used in the UMC St Radboud suppress HIVRNA replication in CSF effectively. Secondary objectives of this study are to investigate the development of HIV resistance in the CSF, whether sufficient (above IC50) drug levels in the CSF can be reached and whether neurocognitive impairment and changes in CSF biomarkers for neurodegeneration appear during treatment.

Study objective

1 To investigate the influence of HAART on CSF viral load, development of HIV resistance, neurotransmitters and biomarkers for neurodegeneration
2 To explore the neurocognitive effects of HIV infection and its treatment
3 To investigate the relationship between CSF drug levels and neurocognitive effects and CSF HIV RNA

Study design

In a group of 40 HIV seropositive patients on HAART therapy the following tests will be done:

- CSF puncture for determination of HIVRNA, drug levels, proteins and biomarkers for neurodegeneration
- neuropsychological tests
- MRI of the brain
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Study burden and risks

pain and discomfort during and after the CSF puncture

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
• On HAART therapy

Exclusion criteria

• Active opportunistic infection
• Active psychiatric disorder for which treatment is indicated
• Malignancy
• Neurosyphilis
• Drug addiction
• Excessive (> 2 U/d) use of alcohol

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	01-04-2009
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	NL25009.091.09