Study in HIV negative controls using BOLD functional MRI

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This study aims to evaluate the frontostriatal cognitive functioning and the functional connectivity in 15 HIV-negative participants using BOLD fMRI.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45334

Source
ToetsingOnline

Brief title
SHERLOC

Condition

- Other condition

Synonym
cognitieve achteruitgang, verstandelijke achteruitgang

Health condition

cognitieve aandoeningen

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: controls, fMRI, HIV-negative

Outcome measures

Primary outcome

Brain activation measured with BOLD fMRI when performing specified tasks

Secondary outcome

Brain activation measured with BOLD fMRI when performing an inhibition task

Brain activation measured with BOLD fMRI when performing a reward task

Brain connectivity measured with BOLD fMRI during resting state

Study description

Background summary

HIV Associated Neurocognitive Disorders (HAND) are a frequent and important comorbidity of HIV-infection. The pathogenesis of this disorder is still not clear. BOLD fMRI is a sensitive and patient-friendly research tool to investigate cognitive functioning, and can aid in unravelling the origins of neurocognitive decline in HIV patients. In the ESCAPE study (METC-no 15/141), we performed fMRI on 40 HIV-positive patients switching combination antiretroviral therapy (cART) comparing them to 20 HIV+ controls. Preliminary results show an effect of cART on cognition. To further unravel these effects and investigate whether HIV infection itself also has an effect, comparing the ESCAPE-results with HIV-uninfected controls will strengthen the outcomes immensely. In fMRI research, it is important to use valid methodology and standardized tasks and equipment, and in HIV research, it is important to use a highly comparable control group. Therefore the proposal of the SHERLOC-study will precisely mimic the previously approved ESCAPE-study, in its study design and execution.

Study objective

This study aims to evaluate the frontostriatal cognitive functioning and the functional connectivity in 15 HIV-negative participants using BOLD fMRI.

Study design

observational longitudinal study

Study burden and risks

participants in the SHERLOC study will be asked to come to the hospital for a total of 3 visits, screening, baseline and week 12 (end of study). At screening, blood will be drawn to test for thyroid or liver pathology. At baseline and week 12, participants will undergo a functional MRI scan, with an average duration of 50 minutes. Measures will be taken to ensure the participant is safe and comfortable in the scanner. When appropriate safety measures are used, MRI is a proven safe diagnostic procedure. There is not a group related benefit for this population. However, information about this population will aid in unravelling the effects of HIV compared to cART in relation to development of HAND.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male, between 25 and 50 years
- HIV-negative at screening visit
- Negative TPHA or VDRL < 12 months prior to or at screening visit
- No signs of an acute or chronic hepatitis C infection within the past 12 months before screening as defined in the Dutch guideline
- No subjective neurocognitive complaints in the preceding 12 months
- Consent to using anonymous patient file
- Able to understand an comply to study procedures and to provide written informed consent

Exclusion criteria

- Proven major depression through psychiatric consultation within the past year or on anti-depressant drugs
- History of proven neurologic disease (e.g. multiple scleroses, brain tumour, cerebrovascular event, etc.)
- Active psychiatric disorders classified according to the DSM V criteria
- History or evidence of alcohol or drug abuse according to the DSM V criteria
- TSH not within normal reference values
- Contraindications for undergoing an MRI according to standard UMCU MRI protocol; a pacemaker or metallic device in situ, proven claustrophobia.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-08-2017
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2017
Application type:	First submission
Review commission:	METC NedMec

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	NL59537.041.16