Antiretroviral therapy and peripheral T cell apoptosis

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

Summary

ID

NL-OMON37267

Source
ToetsingOnline

Brief title
ARTA

Condition

- Viral infectious disorders

Synonym
HIV, Human immunodeficiency virus

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Antiretroviral therapy, apoptosis, HIV, T cell

Outcome measures

Primary outcome

T cell apoptosis is measured by Annexin V and propidium idodide stainings.

Secondary outcome

Furthermore, caspase-activity will be evaluated as well as T cell phenotypes.

Study description

Background summary

Apoptosis is a fundamental mechanism regulating T cell homeostasis and is affected by HIV-disease. Preliminary results from the ACATLIFE-study showed differences in T cell apoptosis between HIV-infected patients with non-nucleoside reverse transcriptase inhibitor (NNRTI)-based treatment compared those with protease inhibitor (PI)-based treatment, however these findings were limited by the set-up and number of included patients.

Study objective

the primary objective is to investigate if HIV-infected patients treated with a NNRTI display higher peripheral T cell apoptosis than those treated with a PI. Secondary objectives are to investigate 1) which apoptosis pathway is involved in antiretroviral treatment (ART)-related T cell apoptosis and 2) which T cell subsets are predominantly affected in ART-related T cell apoptosis.

Study design

This is an observational cross-sectional study on peripheral blood samples.

Study burden and risks

from each subject, a single peripheral blood sample of 18mL (2 tubes) will be required. If possible, the visit will be combined with routine visit to the outpatient clinic at the Department of Internal Medicine and Infectious Diseases. Participation will not provide individual benefit. Group-related

benefits will include a better understanding of adverse effects of (long term-) treatment of HIV.

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

- subjects must be willing and able to provide written informed consent
- Age >18 and <65 years
- Body weight >40 and <125kg
- Infected with HIV-1
- Effective HAART >1 year
- subjects must meet the following criteria per patient group:
o *PI-group* (n=15): HAART must consist of a protease inhibitor (e.g. atazanavir, lopinavir, darunavir), boosted with ritonavir, in combination with backbone therapy consisting of

tenefovir and emtricitabine but without any other antiretroviral medicine.
o *NNRTI-group* (n=15): HAART must consist of a non-nucleoside reverse transcriptase inhibitor (efavirenz, nevirapine) in combination with backbone therapy consisting of tenofovir and emtricitabine without any other antiretroviral medicine.

Exclusion criteria

- Detectable HIV-RNA within 6 months before inclusion
- CD4-count <350
- Switch of HAART within 6 months before inclusion
- Any known pre-existing condition likely to interfere with T cell apoptosis:
o Systemic infections (other than HIV)
o Systemic auto-immune disease
o Systemic immunomodulatory treatment
o Haematologic disease
o Pregnancy
o Immunodeficiency
- Subjects who are closely related to the investigators of the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2012
Enrollment:	33
Type:	Actual

Ethics review

Approved WMO Date:	13-06-2012
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	NL40589.041.12