Biomarkers of the HIV reservoir

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Primary objectivesLongitudinal quantification of the total latent HIV reservoir with determination of the size of the replication competent HIV reservoir and investigate potential biomarkers of the HIV reservoir size and nature.Cross compare the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immunodeficiency syndromes
Study type	Observational invasive

Summary

ID

NL-OMON43497

Source
ToetsingOnline

Brief title
EHEG Biomarkers

Condition

- Immunodeficiency syndromes
- Viral infectious disorders

Synonym
HIV AIDS

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Merck

Intervention

Keyword: Biomarkers, HIV, Reservoir

Outcome measures

Primary outcome

Quantify the size of the reservoir and explore potential biomarkers of the size

and nature of the reservoir.

Secondary outcome

Correlate study findings to other known biomarkers (from other research

groups).

Study description

Background summary

c-ART blocks intracellular HIV-1 replication in CD4+ T-lymphocytes, but fails to eliminate latent HIV-1 infected CD4+ T-lymphocytes. About 7 in 106 of these cells are latently infected and can cause reactivation when c-ART is stopped. For accurate assessment of the impact of potential latency reversing agents (LRA) on the reservoir, a large reservoir is desirable. The biomarkers that are correlated with large circulating latent reservoirs are not well characterised. The purpose of this study is to quantify the reservoir and explore potential biomarkers of the HIV reservoir size.

Study objective

Primary objectives
Longitudinal quantification of the total latent HIV reservoir with determination of the size of the replication competent HIV reservoir and investigate potential biomarkers of the HIV reservoir size and nature.

Cross compare the outcomes of Erasmus and Merck Research Laboratory (MRL) quantitative HIV latency assays.

Secondary objectives
Assessment of T-cell subsets and explore correlation with reservoir size in peripheral blood.
Correlate study findings to known data on biomarkers of the HIV reservoir.

Study design

In vitro observational study.

Study burden and risks

Participation involves visiting the research OPD for blood sampling at enrolment. Follow up blood sampling will be done during routine visits at their HIV physicians. Blood sampling is by standard phlebotomy, which is a very safe procedure. The amount of blood drawn is one fifth of a standard blood donation at the blood bank.

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

1. Age >18 years.
2. Confirmed HIV-1 infection.
3. Plasma HIV RNA viral load <50 copies per mL.
4. Taking cART

Exclusion criteria

1 Anemia, defined as a hemoglobin level of <6.0 mmol/L (women) or <6.5 mmol/L (men).
2 Any other condition that, at the discretion of the investigators, prevents proper informed consent procedure and study participation. This include patients with active and disabling substance use or severe psychiatric disorders.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	22-07-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL56568.078.16