HIV-1 evolution after transmission - A cohort study to identify evolution of recently transmitted HIV-1

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* To study HIV-1 sequence dynamics and HIV-1 evolution in donor-recipient pairs in relation to host and viral factors.* To detect and characterize the differences in transmitted virus in donor-recipient pairs as soon as possible after transmission.

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

Summary

ID

NL-OMON32993

Source ToetsingOnline

Brief title HIV-1 evolution after transmission

Condition

• Viral infectious disorders

Synonym human immunodeficiency virus type1

Research involving Human

Sponsors and support

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

Intervention

Keyword: HIV-1 evolution, Human Leukocyte antigen (HLA), primary HIV-1 infection, viral fitness

Outcome measures

Primary outcome

* Sequence of the viral genome that is present in the HIV-1 donor as close as

possible to the time of HIV-1 transmission.

* Virus diversity (quasispecies) in the donor-recipient pairs half a year after

HIV-1 transmission.

* HLA type of donor-recipient pairs, availability of replication competent

(pseudo)viruses from donor and recipient.

Secondary outcome

The relation between viral sequence dynamics and:

- * The HLA type of donor and recipient
- * The autologous neutralization profile
- * Host CTL responses
- * Viral fitness

Study description

Background summary

It is known that HIV-1 variants escape cellular and humoral immunity in the host. This may however have an impact on viral fitness and as a consequence, escape mutations will revert in the face of declining immunity or upon transmission to a new host. The aim of this study is to examine the dynamics of escape mutations and reversions in relation to the HLA type of the HIV-1 donor and the HLA type of the HIV-1 recipient. In addition, the same HIV-1 sequence dynamics in relation to the specificity of the humoral immune response in HIV-1 donor-recipient pairs will be studied.

Study objective

* To study HIV-1 sequence dynamics and HIV-1 evolution in donor-recipient pairs in relation to host and viral factors.

* To detect and characterize the differences in transmitted virus in donor-recipient pairs as soon as possible after transmission.

Study design

Cohort study

Study burden and risks

Patients will have to come to the outpatient clinic in the AMC at least two times, maximum three. Each visit will take approximately thirty minutes. Sixteen blood samples will be drawn at baseline and 24 wks thereafter with a maximum volume of 128 ml. This may cause some discomfort like a bruise.

There is no individual benefit for the patient to participate in this study, but in general participation will benefit the understanding of the evolution of recently transmitted HIV-1 which is of importance for HIV-1 vaccine development.

Contacts

Public Academisch Medisch Centrum

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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-1 infected partner(s) who are assumed to be the source of HIV-1 transmission (donor) of patients who present with primary HIV-1 infection at the *Primo-SHM* study (recipient) in the AMC (MEC 03/059).

* At least 18 years of age

Exclusion criteria

None

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2009
Enrollment:	30
Туре:	Anticipated

Ethics review

Approved WMO Application type: Review commission:

First submission METC Amsterdam UMC

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 CCMO ID NL26574.018.09