

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26446

### Source

Nationaal Trial Register

### Brief title

HIV evolution after transmission

### Health condition

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

## Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC)

Investigator driven study, no industrial study

**Source(s) of monetary or material Support:** Academic Medical Center (AMC)

Investigator driven study, no industrial study

## Intervention

## Outcome measures

### Primary outcome

1. Sequence of the viral genome that is present in the HIV-1 donor as close as possible to the time of HIV-1 transmission;
2. Virus diversity in the donor-recipient pairs half a year after HIV-1 transmission;
3. 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:

1. The HLA type of donor and recipient;
2. The autologous neutralization profile;
3. Host CTL responses;
4. 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

The aim of this study is to examine the dynamics of escape mutations and reversions in relation to the Human Leukocyte antigen (HLA) type of the HIV-1 donor and the HLA type of the HIV-1 recipient. In addition, the HIV-1 sequence dynamics in relation to the specificity of the humoral immune response in HIV donor-recipient pairs will be studied. Since the donor most likely has an established immune response mounted against HIV-1 whilst the recipient

does not, it may be expected that different viruses will propagate and different cell types will become infected. Hence, the virus in both donor and recipient pairs will be investigated as close as possible to the time of transmission. Simultaneously, the cellular compartments in which HIV resides and replicates will be analyzed.

## **Study design**

1. Screening;
2. Visit 1: baseline;
3. Visit 2: 24 wks after baseline.

## **Intervention**

Venapuncture done twice with 128 ml blood extraction each time.

## **Contacts**

### **Public**

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## **Eligibility criteria**

## Inclusion criteria

1. HIV-1 infected partners 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;
2. At least 18 years of age.

## Exclusion criteria

N/A

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

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

## Ethics review

Positive opinion	
Date:	16-02-2009
Application type:	First submission

## 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
NTR-new	NL1554
NTR-old	NTR1632
Other	MEC AMC : 09/007
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A