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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26446

Bron
Nationaal Trial Register

Verkorte titel
HIV evolution after transmission

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Investigator driven study, no industrial study
Overige ondersteuning: Academic Medical Center (AMC)
Investigator driven study, no industrial study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

It is known that HIV-1 variants escape cellular and humarol 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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Screening;

2. Visit 1: baseline;

3. Visit 2: 24 wks after baseline.

Onderzoeksproduct en/of interventie

Venapuncture done twice with 128 ml blood extraction each time.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-02-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1554
NTR-old	NTR1632
Ander register	MEC AMC : 09/007
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A