Mycophenol mofetil in Antiretroviral Naïve patients 2 (MAN2 study).

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During chronic HIV-1 infection the immune system is chronically hyperactivated. This hyperactivation is considered as the main cause of CD4+ T-cell loss. Furthermore, HIV replicates most efficiently in activated CD4+ T-cells. In this study we try to...

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

Samenvatting

ID

NL-OMON21098

Bron
NTR

Verkorte titel
MAN2

Aandoening

HIV-1 infection

Ondersteuning

Primaire sponsor: AMC-NATEC
Overige ondersteuning: private fund that not wishes to be named

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Endpoints: Primary endpoints are change over time (baseline – week 48) in CD4+ T cell count and peripheral blood lymphocyte (PBMC) activation markers.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

During chronic HIV-1 infection the immune system is chronically hyperactivated. This hyperactivation is considered as the main cause of CD4+ T-cell loss. Furthermore, HIV replicates most efficiently in activated CD4+ T-cells. In this study we try to inhibit the activation of the immune system with mycophenol mofetil (MMF). Previous studies in which HIV-1 infected patients have been treated with MMF in addition to antiretroviral treatment (ART) have not shown any additional effect, compared to ART alone. In this study MMF will be used without antiretroviral medication.

Objectives:

Primary objective of the study is the evaluation of the effect of MMF on the chronic hyperactivation of the immune system and the decrease of the CD4+ T-cell count in chronically HIV-1 infected patients who are not treated with antiretroviral therapy (ART). Secondary objectives include the evaluation of the effect of MMF on plasma HIV-1 RNA; progression of disease/ reaching of indication to start ART; and the safety of treatment with MMF in this patient group.

Study Design:

This is a multi center, randomized, open-label study, in which patients will be randomized to treatment with mycophenol mofetil (MMF) 500 mg BID during 48 weeks versus no treatment. In a subgroup of 20 patients (“immunology group”, the first 20 patients in the AMC hospital, Amsterdam, the Netherlands) a number of additional immunological measurements will be performed.

The study duration is 60 weeks (48 weeks of treatments with 1 additional visit 12 weeks after cessation of treatment).

Study Population:

Potential participants are adult chronically HIV-1 infected patients, who have never been

treated with ART and who according to the present criteria do not need to be treated. CD4+ T lymphocyte count has to be > 250 and <= 450 * 106/L, plasma HIV-1 RNA (viral load) < 10.000 copies/ mL.

Intervention:

Patients will be randomized (1:1) to mycofenol mofetil (MMF) 500 mg BID versus no treatment.

Endpoints:

Primary endpoints are change over time (baseline – week 48) in CD4+ T cell count and peripheral blood lymphocyte (PBMC) activation markers.

Secondary endpoints are changes over time (baseline – week 48) in plasma HIV-1 RNA, time to reach indication to start ART (separated in three groups:

1. two consecutive measurements of CD4+ T cell count below 250 * 106 cells/ L with at least 4 weeks interval;

2. the occurrence of a CDC class B or C event;

3. any other reason); safety data.

Doel van het onderzoek

During chronic HIV-1 infection the immune system is chronically hyperactivated. This hyperactivation is considered as the main cause of CD4+ T-cell loss. Furthermore, HIV replicates most efficiently in activated CD4+ T-cells. In this study we try to inhibit the activation of the immune system with mycophenol mofetil (MMF). Previous studies in which HIV-1 infected patients have been treated with MMF in addition to antiretroviral treatment (ART) have not shown any additional effect, compared to ART alone. In this study MMF will be used without antiretroviral medication.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients will be randomized (1:1) to mycofenol mofetil (MMF) 500 mg BID versus no treatment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient is ≥ 18 years of age;

2. Patient has a proven HIV-1 infection (with antibodies against HIV-1 and a detectable plasma HIV-1 RNA measured for the first time at least 6 months prior to inclusion);

3. Patient is HIV-1 treatment naïve;
CD4+ T lymphocyte count > 250 and <= 450 * 106/L;

4. No signs or history of AIDS defining events;

5. No use of other medications that might possibly influence the effects of MMF;

6. Male; or female sex and willingness to practice effective contraception during the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Plasma HIV-1 RNA < 10.000 copies/ mL;

2. Autoimmune disease;

3. Active hepatitis B or C virus infection;

4. Other chronic diseases;

5. Recent infectious disease other than HIV-1;

6. Treatment with immunomodulatory or anti-inflammatory medication in the past 6 months;

7. For female patients: pregnancy and lactation;

8. Any other condition, illness or use of medication which according to the investigator is not compatible with the use of the study medication or which could interfere with the evaluations required by the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2005
Aantal proefpersonen:	90

Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-09-2005
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	NL388
NTR-old	NTR428
Ander register	: N/A
ISRCTN	ISRCTN43218409

Resultaten

Samenvatting resultaten
N/A