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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21098

Source
NTR

Brief title
MAN2

Health condition

HIV-1 infection

Sponsors and support

Primary sponsor: AMC-NATEC
Source(s) of monetary or material Support: private fund that not wishes to be named

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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.

Study description

Background summary

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;

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Study objective

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.

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2005
Enrollment:	90

Type: Actual

Ethics review

Positive opinion
Date: 15-09-2005

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	NL388
NTR-old	NTR428
Other	: N/A
ISRCTN	ISRCTN43218409

Study results

Summary results
N/A