

Mycophenolate mofetil in Antiretroviral Naive patients 2 (MAN2 study)

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/01/2019	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00120419

Protocol serial number
NTR428

Study information

Scientific Title

Mycophenolate mofetil in Antiretroviral Naive patients 2 (MAN2 study)

Acronym

MAN2

Study objectives

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 mycophenolate 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised open label active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

HIV

Interventions

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

The secondary sponsor for this trial is:

National AIDS Therapy Evaluation Centre (NATEC) (Netherlands)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Change over time (baselineweek 48) in CD4+ T cell count and peripheral blood lymphocyte (PBMC) activation markers.

Key secondary outcome(s))

1. Changes over time (baseline week 48) in plasma HIV-1 RNA
2. Time to reach indication to start ART - separated in three groups:
 - 2.1. Two consecutive measurements of CD4+ T cell count below 250×10^6 cells/l with at least 4 weeks interval
 - 2.2. The occurrence of a CDC class B or C event
 - 2.3. Any other reason
3. Safety data

Completion date

01/03/2007

Eligibility

Key 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 naive
4. CD4+ T lymphocyte count >250 and $\leq 450 \times 10^6/l$
5. No signs or history of AIDS defining events
6. No use of other medications that might possibly influence the effects of MMF
7. Male or female sex and willingness to practice effective contraception during the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key 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

Date of first enrolment

01/03/2005

Date of final enrolment

01/03/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Other

Funder Name

Private fund that does not wish to be named

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

