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Mycophenolate mofetil in Antiretroviral Naive patients 2 (MAN2 study)

Submission date	Recruitment status	[_] Prospectively registered
27/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/01/2019	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00120419

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
HIV

Interventions
Patients will be randomized (1:1) to mycofenolate 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 measure
Change over time (baselineweek 48) in CD4+ T cell count and peripheral blood lymphocyte (PBMC) activation markers.

Secondary outcome measures
1. Changes over time (baselineweek 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 x 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

Overall study start date
01/03/2005

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 ≤450 x 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

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)

Sponsor details
AMC T0-113
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Other

Funder Name
Private fund that does not wish to be named

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration