ISRCTN45284754 https://doi.org/10.1186/ISRCTN45284754

HAART followed by maintenance with monotherapy - Kaletra (MAIMOKA)

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
13/10/2008	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

Protocol serial number
NTR436

Study information

Scientific Title
A randomised controlled trial in human immunodeficiency virus (HIV) positive patients comparing the efficacy of lopinavir/ritonavir monotherapy versus conventional triple therapy

Acronym
MAIMOKA

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS)

Interventions
Experimental arm:
96 weeks of lopinavir/ritonavir; the normal dose of lopinavir/ritonavir 400/100 mg twice daily (BID) will be increased if necessary, depending on trough lopinavir plasma level.

Control arm:
96 weeks of continuation of pre-inclusion triple therapy (HAART).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lopinavir/ritonavir,

Primary outcome(s)
Therapy failure, defined as having a viral load of higher than 400 copies per ml on two consecutive moments in time separated by at least four weeks.

Key secondary outcome(s))
Genotypic resistance of the virus in multiple compartments (plasma, semen, cerebrospinal fluid [CSF]).

Completion date

01/10/2008

Eligibility

Key inclusion criteria
1. Subject is HIV-1-infected
2. Subject is on a first or second line antiretroviral therapy consisting of either one protease inhibitor (PI) or one non-nucleoside reverse transcriptase inhibitors (NNRTI) and at least two nucleoside reverse transcriptase inhibitors (NRTIs)
3. Subject has a HIV-1 ribonucleic acid (RNA) load less than 50 copies/ml for at least three months
4. Ethylenediaminetetraacetic acid (EDTA) plasma from before initiation of first or second line antiretroviral therapy is available for genotyping
5. Subject is at least 18 and not older than 65 years of age
6. Subject is able and willing to sign the informed consent form prior to screening evaluations

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Any mutation in the protease at codon 32, 46, 47, 48, 50, 54, 82, 84 or 90 or more than two mutations in the protease at codon 10, 20, 24, 33, 53, 63, 71, 73
2. Any protease inhibitor regimen failure
3. Any of the following mutations in the reverse transcriptase: M41L, D67N, K70R, L210W, T215Y or T215F, K219Q, K219E, or K65R
4. History of sensitivity/idiosyncrasy to lopinavir/ritonavir
5. Relevant history or current condition that might interfere with drug absorption, distribution, metabolism or excretion
6. Inability to understand the nature and extent of the trial and the procedures required
7. Pregnant female (as confirmed by a human chorionic gonadotropin [HCG] test performed less than three weeks before the first dose) or breast-feeding female
8. Hepatitis B surface antigen (HBsAg) positive hepatitis B infection
9. Abnormal serum liver enzymes or creatinine, determined as levels being greater than three times upper limit of normal
10. Fasting plasma triglyceride level greater than 3.0 mmol/l (= 265.8 mg/dl) in non-Kaletra containing regimens despite the use of lipid lowering drugs
11. Fasting plasma total cholesterol level greater than 6.2 mmol/l (= 239.9 mg/dl) in non-Kaletra containing regimens despite the use of lipid lowering drugs
12. Concomitant use of medications that interfere with lopinavir pharmacokinetics

Date of first enrolment
01/10/2005

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
Abbott International

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration