HAART followed by maintenance with monotherapy-Kaletra (MAIMOKA).

Gepubliceerd: 27-09-2005 Laatst bijgewerkt: 13-12-2022

N/A

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

Samenvatting

ID

NL-OMON20599

Bron
Nationaal Trial Register

Verkorte titel
MAIMOKA

Aandoening

HIV/AIDS

Ondersteuning

Primaire sponsor: VU Medical Center

and

University Medical Center Utrecht
Overige ondersteuning: Abbott International

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Therapy failure, defined as having a viral load of higher than 400 copies per milliliter on two consecutive moments in time separated by at least 4 weeks.

Toelichting onderzoek

Doel van het onderzoek

N/A

Onderzoeksproduct en/of interventie

Experimental arm: 96 weeks of lopinavir/ritonavir; the normal dose of lopinavir/ritonavir 400/100 mg BID will be increased if necessary, depending on trough lopinavir plasma level; Control arm: 96 weeks of continuation of pre-inclusion triple therapy (HAART)

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subject is HIV-1-infected;
2. Subject is on a first or second line antiretroviral therapy consisting of either 1 PI or 1 NNRTI and at least 2 NRTI;
3. Subject has a HIV-1 RNA load < 50 copies/ml for at least 3 months;
4. 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any mutation in the protease at codon 32, 46, 47, 48, 50, 54, 82, 84 or 90 or more than 2 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 an HCG test performed less than 3 weeks before the first dose) or breast-feeding female;
8. HBsAg positive hepatitis B infection;
9. Abnormal serum liver enzymes or creatinine, determined as levels being > 3 times upper limit of normal;
10. Fasting plasma triglyceride level > 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 > 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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-10-2005
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-09-2005
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	NL396
NTR-old	NTR436
Ander register	: N/A
ISRCTN	ISRCTN45284754

Resultaten

Samenvatting resultaten
N/A