

A Randomised, Double-blind, Controlled Study on the Effect of One Year Administration of a Nutritional Concept on Immunological Status in HIV-1 Positive Adults not on Antiretroviral Therapy

Gepubliceerd: 23-01-2007 Laatste bijgewerkt: 13-12-2022

Improving the immunological status of HIV-1 infected adults not on antiretroviral therapy through nutritional support.

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

Samenvatting

ID

NL-OMON21548

Bron

NTR

Verkorte titel

BITE (Blinded nutritional study for Immunity and Tolerance Evaluation)

Aandoening

HIV-1 positive adults not on (HA)ART

Ondersteuning

Primaire sponsor: Numico Research B.V.

Overige ondersteuning: Numico Research B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change from baseline in CD4+ T-cell count during 12 months.

Toelichting onderzoek

Achtergrond van het onderzoek

HIV-1 infection is a major disease. Different pharmaceutical therapies have been developed over the years, turning HIV infection from an acute disease into a chronic disease. The disease is characterized by a progressive deterioration of the immune function, resulting in multiple opportunistic pathologies. Disease progression is monitored by the decrease in the CD4+ T-lymphocyte population, the target cell for viral replication. Apart from the decrease in CD4+ T-cells, many other physiological functions are also altered in the HIV-infected patient as the disease progresses resulting in a decreased overall health status.

This clinical trial will be a multicenter, randomised double-blind study to be executed at a number of clinical trial sites on various continents.

Adult HIV-1 infected patients not on antiretroviral therapy (n=800) will be selected for the trial. Patients will be supplied with either a nutritional test or a control product for a period of 12 months. The change in CD4+ T-cell counts will be monitored at relevant timepoints. In addition, other immune markers as well as viral load will be studied.

Doel van het onderzoek

Improving the immunological status of HIV-1 infected adults not on antiretroviral therapy through nutritional support.

Onderzoeksproduct en/of interventie

Intervention group:

A nutritional concept containing specific selected ingredients.

Control group:

Isocaloric nutritional product with an almost identical appearance and flavour as the investigational product though without the specific selected ingredients.

Patients will be supplied with either a nutritional test or a control product for a period of 12 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Main inclusion criteria:

1. HIV-1 positive adults who have not received (HA)ART in the past year and are not anticipated to start therapy within the next 6 months;
2. HIV-1 RNA > 5,000 copies/ml in the 3 months prior to screening visit;
3. CD4+ T-cell count $\leq$ 800 cells/ μ l in the 3 months prior to screening visit;
4. $\geq$ 18 years old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Main exclusion criteria:

1. (HA)ART anticipated to be required within the next 6 months;
2. Unintended weight loss of more than 10% in the 3 months prior to screening visit.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	23-01-2007
Aantal proefpersonen:	800
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	23-01-2007
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	NL872
NTR-old	NTR886
Ander register	: N/A
ISRCTN	ISRCTN81868024

Resultaten

Samenvatting resultaten

(Abstract (including oral presentation) for) ICAAC 2009, San Francisco