

# A randomised, double-blind, controlled study on the effect of one year administration of a nutritional concept on immunological status in human immunodeficiency virus-1 positive adults not on anti-retroviral therapy

<b>Submission date</b> 26/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/01/2014	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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**

**Secondary identifying numbers**

N/A

## **Study information**

**Scientific Title**

**Acronym**

BITE (Blinded nutritional study for Immunity and Tolerance Evaluation)

**Study objectives**

Improving the immunological status of Human Immunodeficiency Virus-1 (HIV-1) infected adults not on antiretroviral therapy through nutritional support.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received from the Medisch Ethische Commissie AMC on the 20th September 2006 (ref: Internal Numico: 100157; Ethics board: MEC 06/199).

**Study design**

Randomised, placebo controlled, parallel group, double blinded, multicentre trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

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

HIV

**Interventions**

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.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

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

### **Secondary outcome measures**

Changes from baseline during one year in:

1. Immune markers other than CD4+ T-cell count
2. Viral load (HIV-1 RNA)

### **Overall study start date**

23/01/2007

### **Completion date**

30/04/2009

## **Eligibility**

### **Key inclusion criteria**

Main inclusion criteria:

1. HIV-1 positive adults who have not received (Highly Active) Anti-Retroviral Therapy ([HA]ART) in the past year and are not anticipated to start therapy within the next six months
2. HIV-1 Ribonucleic Acid (RNA) more than 5,000 copies/ml in the three months prior to screening visit
3. CD4+ T-cell count less than or equal to 800 cells/ $\mu$ l in the three months prior to screening visit
4. More than or equal to 18 years old

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Not Specified

**Target number of participants**

800

**Key exclusion criteria**

Main exclusion criteria:

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

**Date of first enrolment**

23/01/2007

**Date of final enrolment**

30/04/2009

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

**Numico Research B.V.**

Wageningen

Netherlands

6700 CA

**Sponsor information****Organisation**

Numico Research B.V. (The Netherlands)

**Sponsor details**

P.O. Box 7005

Wageningen

Netherlands

6700 CA

**Sponsor type**

Industry

**Website**

<http://www.numico.com/en/>

**ROR**

<https://ror.org/00aj77a24>

# Funder(s)

## Funder type

Industry

## Funder Name

Numico Research B.V. (The Netherlands)

# 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2013		Yes	No