

# Compliance to six weeks supplementation of a nutritional concept constituted as a powder in HIV-1 positive adults not on Highly Active Anti-Retroviral Therapy (HAART)

<b>Submission date</b> 04/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/05/2011	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**

**Secondary identifying numbers**  
100172

# Study information

## Scientific Title

Compliance to six weeks supplementation of a nutritional concept constituted as a powder in HIV-1 positive adults not on Highly Active Anti-Retroviral Therapy (HAART): an open-label single-centre pilot study

## Acronym

ComBaT II

## Study objectives

Exploratory study to assess whether the product format (nutritional powder) is suitable for long term use in the target population

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Independent Review Board Nijmegen, the Netherlands approved on 25th September 2006

## Study design

Open-label single-centre pilot study

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Human immunodeficiency virus (HIV)-1

## Interventions

Duration of intervention: 6 weeks

Week 1: One sachet containing 45 grams of powder daily

Week 2-6: One sachet containing 45 grams of powder twice daily

The powder had to be dissolved in at least 100 ml cold water or cold dairy products before consumption.

## Intervention Type

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

1. Compliance to intake of a powder
  - 1.1. Total number of study product consumed in 6 weeks
  - 1.2. Average daily intake of study product
  - 1.3. Average weekly intake of study product
  - 1.4. Period of intake of study product
  - 1.5. Change in intake of study product during the study)

## **Secondary outcome measures**

The effect of intake of the powder on:

1. Gastrointestinal tolerance (assessed at baseline, week 3 and week 6)
2. Gut health parameters (assessed at baseline and week 6)
3. Appreciation of the nutritional powder (assessed after first consumption, week 1, week 3 and week 6)

Compare compliance to intake of the powder with compliance to intake of the nutritional bar analysed in the ComBaT study

## **Overall study start date**

16/10/2006

## **Completion date**

27/12/2006

# **Eligibility**

## **Key inclusion criteria**

1. Human immunodeficiency virus (HIV)-1 positive adults who have not received HAART in the past year and are not anticipated to start HAART during the study period
2. Age 18 years and older
3. Males and non-pregnant, non-lactating females
4. CD4+ T-cell count 350 cells/ $\mu$ L or higher
5. Written informed consent

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

**Target number of participants**

30 planned, 24 actual

**Key exclusion criteria**

1. Lactose intolerance (not using a stable dose of lactase) or known allergy for any of the ingredients
2. Unable to adhere to protocol instructions (including illiterate persons)
3. Known inflammatory bowel diseases, coeliac disease
4. Investigators' uncertainty about the willingness or ability of the subject to comply with the protocol requirements [including intravenous (IV) drug users]
5. Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study and during the course of the study

**Date of first enrolment**

16/10/2006

**Date of final enrolment**

27/12/2006

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

Netherlands

**Study participating centre**

Bosrandweg 20

Wageningen

Netherlands

6704 PH

**Sponsor information****Organisation**

Danone Research (Netherlands)

**Sponsor details**

Centre for Specialised Nutrition

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**Sponsor type**

Research organisation

**ROR**

<https://ror.org/01c5aqt35>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Danone Research B.V. (Netherlands) Centre for Specialised Nutrition

**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