

# Compliance to supplementation of a nutritional Bar for six weeks in Highly Active AntiRetroviral Therapy (HAART) - naïve HIV-1 positive adults

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| <b>Submission date</b><br>04/04/2011   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>19/05/2011 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>19/05/2011       | <b>Condition category</b><br>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

### Contact name

Ms Barbara Mourmans

### Contact details

Bosrandweg 20  
Wageningen  
Netherlands  
6704 PH

## Additional identifiers

### Protocol serial number

100158

## Study information

### Scientific Title

Compliance to supplementation of a nutritional bar for six weeks in Highly Active AntiRetroviral Therapy (HAART) - naïve HIV-1 positive adults

### Acronym

ComBaT

### **Study objectives**

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

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Independent Review Board Nijmegen, The Netherlands, 9 May 2006, ref: TC2006004F-HDJ

### **Study design**

Open-label single-centre pilot study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Human immunodeficiency virus (HIV-1)

### **Interventions**

1. Duration of intervention: 6 weeks
2. Week 1: One nutritional bar of 40 grams daily
3. Week 2-6: One nutritional bar of 40 grams twice daily

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

1. Compliance to intake of a nutritional bar
2. Total number of bars consumed in 6 weeks
3. Average daily intake of bars
4. Average weekly intake of bars
5. Period of intake of bars

### **Key secondary outcome(s))**

The effect of intake of the nutritional bar on:

1. Gastrointestinal tolerance (assessed at baseline, week 3 and week 6)
2. Gut health parameters (assessed at baseline and week 6)
3. Activation markers in blood (assessed at baseline and week 6)
4. Appreciation of the nutritional bar (assessed after first consumption, week 1, week 3 and week 6)

### **Completion date**

22/08/2006

## Eligibility

### Key inclusion criteria

1. HAART - naïve adults with confirmed HIV-1 infection
2. Age 18 years and older
3. Males
4. Non-pregnant, non-lactating females
5. CD4+ T-cell counts 400 cells/ $\mu$ L or higher at screening
6. Written informed consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Key exclusion criteria

1. Lactose intolerance or known allergy for any of the ingredients
2. Unable to adhere to protocol instructions (including illiterate persons)
3. Known inflammatory bowel diseases
4. Coeliac disease
5. Investigators' uncertainty about the willingness or ability of the subject to comply with the protocol requirements (IV drug users are considered as probably non-compliant)
6. Anticipated to start HAART during the study period
7. 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

20/06/2006

### Date of final enrolment

22/08/2006

## Locations

### Countries of recruitment

Netherlands

**Study participating centre**  
**Bosrandweg 20**  
Wageningen  
Netherlands  
6704 PH

## Sponsor information

**Organisation**  
Danone Research (Netherlands)

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

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Danone Research B.V. (The Netherlands) Centre for Specialised Nutrition

## Results and Publications

**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="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |