

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)

Submission date 04/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/05/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/05/2011	Condition category 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

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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)

Key secondary outcome(s)

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

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/ μ L or higher
5. 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 (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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration