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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

Registration date
19/05/2011

Last Edited
20/05/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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

Primary study design
Interventional

Study design
Open-label single-centre pilot study

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/µL 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