ISRCTN76848857 https://doi.org/10.1186/ISRCTN76848857

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

Submission date	Recruitment status	[_] Prospectively registered
04/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2011	Infections and Infestations	[_] 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
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/µL 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes