

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

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 19/05/2011	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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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)

Overall study start date

20/06/2006

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/ μ L or higher at screening
6. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30 planned, 27 actual

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)

Sponsor details

Centre for Specialised Nutrition

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Sponsor type

Industry

Website

http://www.research.danone.com/means_to_succeed/the_research_center/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

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