ISRCTN81868024 https://doi.org/10.1186/ISRCTN81868024

A randomised, double-blind, controlled study on the effect of one year administration of a nutritional concept on immunological status in human immunodeficiency virus-1 positive adults not on anti-retroviral therapy

Submission date
26/02/2007

Registration date
26/02/2007

Last Edited
06/01/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
BITE (Blinded nutritional study for Immunity and Tolerance Evaluation)

Study objectives
Improving the immunological status of Human Immunodeficiency Virus-1 (HIV-1) infected adults not on antiretroviral therapy through nutritional support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medisch Ethische Commissie AMC on the 20th September 2006 (ref: Internal Numico: 100157; Ethics board: MEC 06/199).

Study design
Randomised, placebo controlled, parallel group, double blinded, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
HIV

Interventions
Intervention group:
A nutritional concept containing specific selected ingredients.

Control group:
Isocaloric nutritional product with an almost identical appearance and flavour as the investigational product though without the specific selected ingredients.

Patients will be supplied with either a nutritional test or a control product for a period of 12 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Change from baseline in CD4+ T-cell count during 12 months.

Secondary outcome measures
Changes from baseline during one year in:
1. Immune markers other than CD4+ T-cell count
2. Viral load (HIV-1 RNA)

Overall study start date
23/01/2007

Completion date
30/04/2009

Eligibility

Key inclusion criteria
Main inclusion criteria:
1. HIV-1 positive adults who have not received (Highly Active) Anti-Retroviral Therapy ([HA]ART) in the past year and are not anticipated to start therapy within the next six months
2. HIV-1 Ribonucleic Acid (RNA) more than 5,000 copies/ml in the three months prior to screening visit
3. CD4+ T-cell count less than or equal to 800 cells/µl in the three months prior to screening visit
4. More than or equal to 18 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
800

Key exclusion criteria
Main exclusion criteria:
1. (HA)ART anticipated to be required within the next six months
2. Unintended weight loss of more than 10% in the three months prior to screening visit

Date of first enrolment
23/01/2007

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Numico Research B.V.
Wageningen
Netherlands
6700 CA

Sponsor information

Organisation
Numico Research B.V. (The Netherlands)

Sponsor details
P.O. Box 7005
Wageningen
Netherlands
6700 CA

Sponsor type
Industry

Website
http://www.numico.com/en/

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V. (The Netherlands)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No