

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

Recruitment status

No longer recruiting

Prospectively registered

Protocol

Registration date

26/02/2007

Overall study status

Completed

Statistical analysis plan

Results

Last Edited

06/01/2014

Condition category

Infections and Infestations

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Changes from baseline during one year in:

1. Immune markers other than CD4+ T-cell count
2. Viral load (HIV-1 RNA)

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/ μ l in the three months prior to screening visit
4. More than or equal to 18 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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)

ROR
<https://ror.org/00aj77a24>

Funder(s)

Funder type
Industry

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

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?
Results article	results	01/07/2013		Yes	No