The effect of a nutritional supplement (NR100103-2) on digestive health in HIV-1 positive adults with increased gut permeability

	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
	Record updated in last year
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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

100103-2

Study information

Scientific Title

The effect of nutritional supplementation with NR100103-2 on gut health parameters in HIV-1 positive adults with increased gut permeability

Acronym

Ntegra

Study objectives

In this proof of concept study it was investigated whether 8 weeks of supplementation with NR100103-2 would contribute to improved gut health

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee, Center of the Foundation for Infectious Disease Studies (Comité de ética FUNCEI) (Argentina), 24/08/2005

Study design

Proof of concept, double blind, randomised controlled parallel-group two arm multicentre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV-1)

Interventions

- 1. Duration of intervention: 8 weeks
- 2. Intervention group: 1 sachet of NR100103-2 once daily for 8 weeks
- 3. Control group: 1 sachet of control once daily for 8 weeks
- 4. One sachet contained 19 grams of powder and had to be mixed in water or juice and consumed orally

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Gut permeability after 8 weeks of supplementation with NR100103-2

Secondary outcome measures

The effect of supplementation of NR 100103-2:

- 1. For 8 weeks on levels of gut inflammation
- 2. For 4 weeks on gut permeability
- 3. For 4 weeks and 8 weeks on gut absorption
- 4. 8 weeks on immune factors in faeces and serum
- 5. 8 weeks on faecal flora
- 6. Safety parameters

Overall study start date

24/11/2005

Completion date

01/02/2007

Eligibility

Key inclusion criteria

- 1. Adults with confirmed HIV-1 infection
- 2. At least 18 years of age
- 3. Males
- 4. Non-pregnant (confirmed by pregnancy test) females
- 5. Non-lactating females
- 6. Have not received antiretroviral treatment within past six months, and no antiretroviral treatment anticipated to be required during the study period
- 7. Abnormal gut permeability (defined as abnormal urine ratio of lactulose /rhamnose (L/R ratio) at screening)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

78 planned, 87 actual

Key exclusion criteria

- 1. HIV-2 infection
- 2. Regular NSAIDs intake within two weeks prior to screening and during study
- 3. Known inflammatory bowel diseases, coeliac disease
- 4. Known gut bacterial infections /overgrowth
- 5. Known diabetes type 1, 2
- 6. Lactose intolerance
- 7. Clinical renal failure
- 8. Known liver dysfunction
- 9. Acute febrile illness
- 10. Current antibiotic use
- 11. Current use of corticosteroids or other immune modulating medications
- 12. Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol requirements, such as drug or alcohol abuse, mental disorder
- 13. Participation (or intention to participate) in any other studies involving investigational or marketed products concomitantly or within four weeks prior to entry into the study

Date of first enrolment

24/11/2005

Date of final enrolment

01/02/2007

Locations

Countries of recruitment

Argentina

Brazil

England

United Kingdom

Study participating centre Chelsea & Westminster Hospital London

London United Kingdom SW10 9NH

Sponsor information

Organisation

Danone Research (Netherlands)

Sponsor details

Centre for Specialised Nutrition Bosrandweg 20 Wageningen Netherlands 6704 PH +31 317 467 800 barbara.mourmans@danone.com

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. (Tthe 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