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

Submission date	Recruitment status	[ ] Prospectively registered
01/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/05/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/02/2017	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

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
United Kingdom
SW10 9NH

Sponsor information

Organisation
Danone Research (Netherlands)

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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. (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