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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Gut permeability after 8 weeks of supplementation with NR100103-2

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Argentina

Brazil

Study participating centre
Chelsea & Westminster Hospital
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Danone Research (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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes