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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

## Primary study design
Interventional

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

## 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