

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

<b>Submission date</b> 01/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/02/2017	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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