

Tolerance and immunological response in human immunodeficiency virus (HIV) seropositive individuals after NR100063 supplementation

Submission date 05/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/12/2011	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Tolerance and immunological response in human immunodeficiency virus (HIV) seropositive individuals after NR100063 supplementation: a randomised double-blind placebo-controlled three-arm parallel study

Acronym

COPA

Study objectives

H0: No difference between Group 1 (Copa 2x dose), Group 2 (Copa 1x dose) and the control group on variable

H1: At least two of the three treatments differ from each other

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local ethics approval (Comitato Etico Ospedale Luigi Sacco, Milano, Italy) given on the 1st April 2005 (ref: 125/2005 3)

Study design

Randomised double-blind placebo controlled three-arm parallel 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 details below to request a patient information sheet

Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV)

Interventions

Group 1 (n = 20): Double dose; supplementation for 12 weeks plus 4 weeks supplement-free follow up

Group 2 (n = 20): Single dose; supplementation for 12 weeks plus 4 weeks

supplement-free follow up

Group 3 (n = 20): Placebo/control; supplementation for 12 weeks plus 4 weeks supplement-free follow up

Dose regimen: 3 times daily x 16 grams = 48 grams of powder per day (for all three arms). Of these 48 grams, the double dose group received 30 grams of NR100063, the single dose group 15 grams of NR100063. The remainder of the product consisted of inert sugars and maltodextrin. The placebo group received 48 grams of maltodextrin. The powder was to be dissolved in water or juice, or mixed with yoghurt.

Duration of study: 16 weeks

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

NR100063

Primary outcome measure

The determination of tolerance and safety during the supplementation period. Blood samples drawn at baseline, week 4, week 12 and week 16 and tolerance was assessed at each visit using recall questionnaire.

Secondary outcome measures

To establish the effects of supplementation on biomarkers:

1. HIV immune biomarkers
2. Gut activity assessed by faecal biomarkers
3. Viral load
4. CD4 counts

Blood samples drawn at baseline, week 4, week 12 and week 16 and stool samples were collected at baseline and after 12 weeks.

Overall study start date

01/06/2005

Completion date

08/08/2006

Eligibility

Key inclusion criteria

1. Treatment-naïve HIV-positive individuals with no stage 3 illness
2. At least 18 years of age
3. Males or non-pregnant, non-lactating females
4. Never received antiretroviral treatment
5. CD4+ T-cell counts between 400 and 800 cells/uL
6. Plasma HIV-1 ribonucleic acid (RNA) levels between 1,000 and 65,000 copies/mL

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60 planned; 57 actual (stopped after interim analysis)

Key exclusion criteria

1. Self reported vaccination during the 2 months prior to inclusion, or intention to be vaccinated during study period
2. Acute febrile illness
3. Current antibiotic use
4. Current use of corticosteroids or other immune modulating medications
5. Self reported history of IL-2 administration or other vaccine candidates in the past 5 years
6. The use of probiotics or fibres in nutritional health products or supplements
7. 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
8. 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

01/06/2005

Date of final enrolment

08/08/2006

Locations**Countries of recruitment**

Italy

Study participating centre

Ospedale Luigi Sacco

Milano

Italy

20157

Sponsor information

Organisation

Danone Research B.V. (Netherlands)

Sponsor details

Centre for Specialised Nutrition

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Sponsor type

Industry

Website

<http://www.danone.com/en/research-innovations.html>

ROR

<https://ror.org/01c5aqt35>

Funder(s)**Funder type**

Industry

Funder Name

Danone Research B.V. (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2008		Yes	No
Results article	results	01/09/2011		Yes	No