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

Submission date 05/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/07/2010	**Overall study status** Completed	
Last Edited 21/12/2011	**Condition category** Infections and Infestations	

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

100063

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