ISRCTN43435738 https://doi.org/10.1186/ISRCTN43435738

Effect of symbiotic administration on selected health indices in a human volunteer trial (dietary intervention)

Submission date	Recruitment status	[ ] Prospectively registered
16/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/07/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/09/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Marika Mikelsaar

Contact details
Ravila 19
Tartu
Estonia
50411
+372 (0)7 374 179
marika.mikelsaar@ut.ee

Additional identifiers

Protocol serial number
96/94

Study information

Scientific Title

Study objectives
The consumption of probiotic and prebiotic agents' influence on the human gastrointestinal ecosystem that may manifest the possible shifts in health indices in response to symbiotic intake.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Review Committee on Human Research of the University of Tartu on 21 /08/2001, reference number: 96/94

Study design
Randomised double-blind dietary (symbiotic) cross-over intervention study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy adults

Interventions
Symbiotic consumption versus placebo capsule. Volunteers were randomly allocated to receive either:
1. One sachet of prebiotic (6.6 g Raftilose®; P95) and two capsules of the freeze-dried probiotics (Lactobacillus fermentum ME-3, Lactobacillus paracasei 8700:2, Bifidobacterium longum 46; 3 x 10^9 colony forming units [CFU]) per day
2. Placebo (maltodextrin) twice a day for three weeks
After a two-week washout period, volunteers were crossed over to another three weeks of symbiotic or placebo administration.

Details of Joint Sponsor:
Estonian Science Foundation
Sihtasutus Eesti Teadusfond
Endla 4, Tallinn
Estonia
http://www.etf.ee/

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome measure is to assess the effect of symbiotic intake on health indices, biochemical markers, and faecal microflora

Key secondary outcome(s))

1. To assess the health indices of healthy adults (body mass index, blood pressure, bone mineral density)
2. The self-reported questionnaire was applied containing questions on welfare, nutritional habits, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency)
3. All subjects completed a modified semi-quantitative questionnaire about their nutritional habits
4. To determine haematological indices (haemoglobin, white blood cell count, red blood cells, platelets), plasma glucose, total cholesterol (TC), low-density lipoprotein-cholesterol (LDL), high-density lipoprotein-cholesterol (HDL), triglyceride and high-sensitive C-reactive protein (hsCRP) levels
5. To determine total antioxidative activity (TAA), total antioxidative status (TAS), oxidized low density lipoprotein (oxLDL), baseline diene conjugates of LDL (BDC-LDL) in blood samples
6. To determine in urine the content of 8-isoprostanes and biogenic amines
7. Faecal samples were analysed for presence of Helicobacter pylori antigen by the Helicobacter pylori stool antigen (HpSA) test (ImmunoCard STAT HpSA, Meridian Bioscience Europe, Italy)
9. Fluorescence in situ hybridisation (FISH) was used to monitor changes in faecal microflora after consumption of synbiotic

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Wish to participate in the study
2. Aged 20-60 years
3. Healthy (i.e. no known health problems and no medical conditions that require drug therapy)
4. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. History of any gastrointestinal disease
2. Use of any antimicrobial drug within last month
3. Use of any regular concomitant medication, including medical preparations
4. Pregnancy or breastfeeding
5. Food allergy

Date of first enrolment

17/02/2005

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Estonia

Study participating centre
Ravila 19
Tartu
Estonia
50411

Sponsor information

Organisation
EU Commission (Belgium)

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
EU Commission

Funder Name
Estonian Science Foundation (Estonia)

Alternative Name(s)
Estonian Science Foundation, ETF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Estonia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration