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Selection of lactobacilli in biodefence

Submission date 22/08/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 31/10/2008	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 31/10/2008	**Condition category** Digestive System	[ ] Individual participant data [ ] 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
142/7

Study information

Scientific Title
Rapid induction of passive immunity against weapon of bioterrorism using transformed GRAS (generally regarded as safe) bacteria

Acronym
Biodefence

Study objectives

To evaluate the safety of consumption of high doses of lactobacilli on selected health indices and to assess the persistence of consumed lactobacilli strains in gastrointestinal tract.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Committee (ERC) on Human Research at the University of Tartu gave approval on the 24th October 2005 (ref: 142/7)

Study design
Interventional, single-arm, open trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Passive immunity against weapon of bioterrorism

Interventions
Fifteen participants (9 women and 6 men) were enrolled in this study. Volunteers received capsules of the freeze-dried putative probiotics (L. gasseri 177, L. acidophilus 821-3, L. gasseri E16B7, L. paracasei 317 and L. fermentum 338-1-1, 10^10 cfu each) orally for 5 days. Blood analyses were taken to exclude the infection and to test putative adverse effect of consumed lactobacilli. The persistence of lactobacilli was detected in faecal samples.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lactobacilli

Primary outcome(s)
1. No adverse effect after consumption according to clinical, blood and intestinal indices. Timepoints of assessment: at recruitment and end of the study (day 20).
2. The best coloniser from the five tested Lactobacillus strains was detected at the end of the study (day 20)

Key secondary outcome(s))
Colonisation by L. acidophilus 821-3 confirmed by real time polymerase chain reaction (PCR) in faecal samples at the end of the study (day 20)

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. Both males and females, aged 20 - 70 years
2. Wish to participate in the study
3. Healthy (i.e. no known health problems and no medical conditions that require drug therapy)
4. Informed consent obtained

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/breastfeeding
5. Food allergy

Date of first enrolment
01/10/2006

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Estonia

Study participating centre
University of Tartu
Tartu
Estonia
50411

Sponsor information

Organisation
Estonian Science Foundation (Estonia)

Funder(s)

Funder type
Government

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

Funder Name
EU Commission (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration