

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

Contact name

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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)

Primary study design

Interventional

Study design

Interventional, single-arm, open trial

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