

# Selection of lactobacilli in biodefence

<b>Submission date</b> 22/08/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/10/2008	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Tartu  
Estonia  
50411

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## **Secondary study design**

Non randomised controlled trial

## **Study setting(s)**

Other

## **Study type(s)**

Diagnostic

## **Participant information sheet**

## **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 measure**

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)

**Secondary outcome measures**

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)

**Overall study start date**

01/10/2006

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

15

**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)

### Sponsor details

Endla 4

Tallinn

Estonia

10142

### Sponsor type

Government

### Website

<http://www.etf.ee/index.php?setlang=eng>

## 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**

**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