ISRCTN53164826 https://doi.org/10.1186/ISRCTN53164826

# Probiotic capsule trial

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 18/04/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 24/05/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 23/05/2008 | Nutritional, Metabolic, Endocrine | |

**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**
121/6

## Study information

**Scientific Title**

## Study objectives
In non-diseased host the probiotic health claims could be assessed by improvement of some measurable laboratory indices of well-established physiological functions of host, e.g. markers of antioxidative defense system.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Not Specified

## Participant information sheet

## Health condition(s) or problem(s) studied
Healthy subjects

## Interventions
Probiotic capsule versus placebo capsule.
1. The study group members (8 males and 4 females) took three probiotic containing capsules (8.4 log colony forming unit [CFU] per capsule) two times daily (daily dose 9.2 log CFU) for three weeks.
2. The placebo group (7 males and 5 females) received identical capsules without the probiotic strain.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Probiotic

## Primary outcome measure

Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/2004

### Completion date
30/04/2004

## Eligibility

### Key inclusion criteria
Inclusion criteria included the wish to participate, no known health problems, no medical conditions requiring drug therapy, no other yoghurts or no special diets.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
24 adult volunteers (15 men and 9 women)

### Key exclusion criteria
Subjects with a history of gastrointestinal tract (GIT) disease, food allergy and acute infection, use of any antimicrobial agent within the last month or use of any regular concomitant medication were excluded.

### Date of first enrolment
01/01/2004

### Date of final enrolment
30/04/2004

## Locations

### Countries of recruitment
Estonia

### Study participating centre
**Ravila 19**
Tartu

Estonia
50411

# Sponsor information

**Organisation**
Estonian Science Foundation (Estonia)

**Sponsor details**
Kohtu 6
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**Sponsor type**
Government

# Funder(s)

**Funder type**
Government

**Funder Name**
Estonian Science Foundation ( base funding ref 0418 and 5327)

**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

**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 | 04/08/2005 | | Yes | No |