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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