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The effect of probiotic strains on intestinal permeability in well-trained adults

Submission date 06/11/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/11/2015	**Overall study status** Completed	
Last Edited 21/01/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Probiotics are live bacteria and yeasts that are good for your health. They are often found in milk products such as yogurt and as food supplements. It is believed that regular consumption of probiotics has a beneficial effect on the digestive system. This study will investigate whether a capsule with a specific probiotic microorganism can improve intestinal permeability more than a capsule that does not contain probiotics (placebo).

Who can participate?
Healthy men and women aged 18 to 40 who train for 4 or more hours per week and experience gastrointestinal symptoms that interfere with their training and during competition.

What does the study involve?
Participants are randomly allocated to take either one of two capsules containing two different probiotics or an identical capsule without probiotics (placebo) for 6 weeks. Participants provide urine and fecal samples, undergo exercise tests, and complete questionnaires on quality of life, food habits, physical activity and bowel habits.

What are the possible benefits and risks of participating?
The consumption of the probiotic capsule could lead to a general improvement in the partcipant' s well-being and has no known risks.

Where does the study take place?
Nutrition-Gut-Brain Interactions Research Centre (NGBI), Örebro University, Sweden

When is the study starting and how long is it expected to run for?
January 2015 to February 2016

Who is funding the study?
Chr. Hansen A/S (Denmark)

Who is the main contact?
Prof Robert Brummer

Contact information

Type(s)
Scientific

Contact name
Mr Adam Baker

Contact details
Boege Alle 10-12
Hoersholm
Denmark
2970

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HND-GI-020

Study information

Scientific Title
Investigational study on the effect of 6 weeks intake of two probiotic strains on exercise-induced intestinal permeability – a randomized, double-blind, placebo-controlled, three-armed parallel group study

Acronym
APRO

Study objectives
The study was designed to investigate the efficacy of daily consumption of two probiotic strains for 6 weeks on exercise-induced intestinal permeability and supporting biomarkers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regionala etikprövningsnämnden (Regional Ethical Committee) i Uppsala, 18/03/2015 , ref: Dnr 2015/077

Study design
Randomized double-blind placebo-controlled parallel-group study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Gastrointestinal function

Interventions
Participants are randomised to one of three treatment arms for six weeks:
1. A capsule containing a probiotic strain A
2. A capsule containing a probiotic strain B
3. A placebo capsule with no probiotics

Intervention Type
Supplement

Primary outcome measure
Intestinal permeability after a standardized exercise challenge measured by the in vivo lactulose /rhamnose sugar test at baseline and end of intervention (after 6 weeks)

Secondary outcome measures
Multiple potential biomarkers measured in blood, feces and saliva at baseline and end of intervention (after 6 weeks)

Overall study start date
01/01/2015

Completion date
01/02/2016

Eligibility

Key inclusion criteria
1. Healthy men or women
2. Age 18 to 40 inclusive
3. Presence of upper or lower gastrointestinal symptoms that interfere with training and during

competition
4. Weekly training load of 4 or more hours within endurance sports (minimum 50% of the training should be running activity)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
1. History of hypersensitivity to any of the ingredients of the study products or lactose intolerance
2. History or diagnosis of gastrointestinal disease or complicated gastrointestinal surgery
3. Any physical or psychological abnormality or medical condition that could have an effect on gastrointestinal discomfort
4. Participation in any other clinical study
5. Not willing or able to provide written informed consent for participation in the study
6. For women: Not willing and able to use a reliable contraceptive method, pregnancy, lactation or wish to become pregnant

Date of first enrolment
21/09/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Örebro University
Nutrition-Gut-Brain Interactions Research Centre (NGBI)
Sweden
701 82

Sponsor information

Organisation
Chr. Hansen A/S (Denmark)

Sponsor details
Boege Alle 10-12
Hoersholm
Denmark
2970

Sponsor type
Industry

ROR
https://ror.org/01mv6bt66

Funder(s)

Funder type
Industry

Funder Name
Chr. Hansen A/S (Denmark)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/05/2024	21/01/2025	Yes	No