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

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

### 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

#### Protocol serial number

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

# Study type(s)

**Not Specified** 

### 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(s)

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)

### Key secondary outcome(s))

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

### 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

# Healthy volunteers allowed

No

### Age group

Adult

# Lower age limit

18 years

#### Sex

Αll

### 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)

### **ROR**

https://ror.org/01mv6bt66

# Funder(s)

### Funder type

Industry

### **Funder Name**

# **Results and Publications**

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes