

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

Submission date 06/11/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2025	Condition category Digestive System	<input type="checkbox"/> 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 participant'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