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The effect of probiotics on the absorption of essential nutrients from plant protein

Submission date
06/01/2020

Recruitment status
No longer recruiting

Registration date
08/01/2020

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Different types and quality of dietary protein can affect the absorption of essential nutrients (amino acids) following protein supplementation. Compared to animal protein sources, plant protein sources, with the exception of soy protein, are incomplete proteins lacking in one or more essential amino acids. Through optimizing gut bacteria (microbiota) composition, certain strains of live bacteria (probiotics) have been linked to improved nutrient absorption, including protein utilization. Different types and quality of dietary protein can affect amino acid absorption following protein supplementation. Compared to animal protein sources such as pea are incomplete proteins lacking in one essential amino acid. In addition, plant proteins contain less branched-chain amino acids (BCAAs), especially leucine, one of the crucial amino acids for muscle health, especially the activation of muscle protein synthesis. Plant proteins differ in absorption kinetics and the amount of amino acids absorbed by the host. Therefore, there is an interest in nutritional strategies to improve or raise the blood amino acid concentrations after ingesting a plant protein source to overcome compositional shortcomings. The purpose of this study is to investigate the effect of probiotic supplementation on amino acid absorption of plant proteins.

Who can participate?
Healthy men between the ages of 18–35 years, with normal body weight, who are recreationally active.

What does the study involve?
Participants are randomly allocated to receive a supplement containing vegetable protein and probiotic bacteria or vegetable protein alone for two weeks. After a four week period the participants will take the opposite supplement for two weeks.

What are the possible benefits and risks of participating?
The results of this study can be utilized to develop an effective probiotic supplement that could be used to enhance the appearance of amino acids in the blood and potentially recovery from exercise and sport participation, or reduce age-related muscle loss.
Risks of the blood sampling procedure include bruising, hematoma, dizziness, fainting, pain upon needle stick, and the remote risk of infection. These risks will be minimized by having trained

personnel obtain blood samples using standard procedures and, sterile, single use phlebotomy supplies.

Where is the study run from?
1. Texas Christian University, USA
2. University of Mary Hardin-Baylor, USA

When is the study starting and how long is it expected to run for?
August 2017 to October 2019

Who is funding the study?
1. Sofar S.p.A., Italy
2. Increnovo LLC, USA

Who is the main contact?
Dr Ralf Jäger
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
INC2017-PROPLAPRO5

Study information

Scientific Title
The effect of L. paracasei LP-DG® (CNCM I-1572) and L. paracasei LPC-S01 (DSM 26760) administration on amino acid absorption from plant protein – A placebo-controlled, randomized, double-blind, multicenter, crossover study

Study objectives
Growing transition to more plant-based, whole-foods, sustainable diets raised questions about the protein adequacy of vegetarian and vegan diets. In addition, a reduction of animal protein intake, in particular meat consumption, has recently become more prevalent in Western countries. Plant proteins differ in digestibility and amino acid composition from animal proteins. Specifically, plant proteins such as pea or rice are lower in leucine and total BCAA content, amino acids that have been linked to muscle health by activating muscle protein synthesis. Through optimizing gut microbiota composition, specific probiotic strains have been linked to improved nutrient absorption, including protein utilization. While lactic acid bacteria (LAB) have proteases and peptidases that provide the bacteria with free amino acids for optimal growth, they are not classified as strongly proteolytic bacteria. The role of LAB such as Lactobacillus paracasei on protein digestion and absorption of amino acids by the host is currently unknown.
Thus, the purpose of this study was to investigate the individual and potential additive or synergistic effects of L. paracasei LP-DG® and/or L. paracasei LPC-S01 on the in vitro digestion of different plant protein sources, in conjunction with a human study investigating blood amino acid concentrations after co-administration of plant protein and probiotics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 31/07/2017, Institutional Review Board of Texas Christian University (Fort Worth, TX, USA; tel. not provided; email not provided), ref: 1707-080-1707
2, Approved 04/01/2019, The University of Mary Hardin-Baylor (Belton, Texas, USA; tel. not provided; irb@umhb.edu), ref: Protocol #44

Study design
Interventional placebo-controlled randomized double-blind multicenter crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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
Healthy individuals

Interventions
Co-administration of 20 g of protein (vegetable protein isolated from yellow pea (Pisum Sativum), NUTRALYS® S85F, Roquette Freres S.A., France) with either 10 billion CFU of a multi-strain probiotic (5 billion CFU L. paracasei LP-DG® (CNCM I-1572) and 5 billion CFU L. paracasei LPC-S01 (DSM 26760), AminoAlta™, SOFAR S.p.A., Italy) or a placebo (maltodextrin, Glucidex® 12, Roquette Freres S.A., France).

The study consisted of a two week supplementation period, followed by a four week washout, followed by a crossover of groups and another two weeks of supplementation. As for the randomization process, we used Random.org to randomize everyone as they came into the lab. We assigned the A treatment as 1 and the B treatment as 2 and the website gave us a number for that person.

Intervention Type
Supplement

Primary outcome measure
Plasma amino acid concentrations measured using tandem-mass spectrometry (LC/MS/MS) at baseline, 30, 60, 120, and 180 minutes post-ingestion

Secondary outcome measures
Adverse events throughout the study measured using case report forms

Overall study start date
01/05/2017

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Healthy men between the ages of 18–35 years
2. Normal body weight (body mass index (BMI) of 19 – 24.99 kg/m²)
3. Recreationally active (according to American College of Sports Medicine Guidelines)
4. Subjects were not allowed to consume any nutritional or ergogenic supplement known to affect measures of the current study for the prior six weeks, including probiotics, prebiotics and digestive enzymes

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
15

Total final enrolment
15

Key exclusion criteria
1. Currently being treated for or diagnosed with a gastrointestinal, cardiac, respiratory, circulatory, musculoskeletal, metabolic, immune, autoimmune, psychiatric, hematological, neurological or endocrinological disorder
2. Not weight stable defined as measured body mass deviating by 2% or more
3. Not willing to abstain from alcohol, nicotine, and caffeine for 12 hours prior to each visit

Date of first enrolment
01/08/2017

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Texas Christian University
2800 S University Dr
Fort Worth
United States of America
76129

Study participating centre
University of Mary Hardin-Baylor
900 College St
Belton
United States of America
76513

Sponsor information

Organisation
Sofar (Italy)

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Sponsor type
Industry

Website
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ROR
https://ror.org/04f3x2j17

Funder(s)

Funder type
Industry

Funder Name
SOFAR S.p.A.

Funder Name
Increnovo LLC

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	15/10/2020	Yes	No