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Effects of probiotic (BC30) supplementation on exercise-induced muscle damage, perceived recovery and athletic performance

Submission date
28/08/2015

Recruitment status
No longer recruiting

Registration date
07/09/2015

Overall study status
Completed

Last Edited
10/10/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The human gut plays host to tens of trillions of different bacteria, which are known as the “gut flora”. The bacteria present in the gut flora are often referred to as “good” or “friendly” bacteria, because they assist in digestion and help to produce important vitamins for the body. Probiotics, which usually come in the form of supplements or drinks, are live bacteria which are promoted as being extremely beneficial for health, as they are thought to replenish levels of “good bacteria” in the gut. Many studies have shown that probiotic supplements can help to support a healthy digestive and immune system. It has also been shown that probiotics can help to increase the amounts of essential nutrients, such as proteins, that are absorbed in the gut. An initial study has shown that consuming probiotics and protein together can help improve performance in athletes during resistance training (weight training). It is well established that protein can help to prevent and repair muscle damage following exercise, and this study aims to find out whether consuming protein and probiotics together can help to speed up muscle recovery and reduce muscle damage following a damaging exercise bout, as well as boosting athletic performance.

Who can participate?
Healthy men between 18 and 25 years of age, who take part in sports recreationally (not professionally).

What does the study involve?
At the start of the study, each participant is given time to get used to the different exercises that are used in the study. All participants are then asked to consume 20g casein (protein found in milk products) every day for two weeks. They then complete a bout of potentially muscle-damaging exercise. Markers of muscle damage, recovery and athletic performance are then measured at 24 hour intervals over 72 hours. After a one week break, participants then consume 20g casein as well as the pro-biotic (GanedenBC30) every day for two weeks, after which the exercises and measurements are repeated, at 24 hour intervals over 72 hours.

What are the possible benefits and risks of participating?
A benefit of participating is that the results of this study will provide athletes with a nutritional alternative to reduce the negative effects of training. Possible risks include pain during the collection of the blood sample and injury during the exercise.

Where is the study run from?
Department of Health Sciences and Human Performance, University of Tampa, Florida (USA)

When is the study starting and how long is it expected to run for?
July 2014 to May 2015

Who is funding the study?
Ganeden Biotech Inc. (USA)

Who is the main contact?
Dr Ralf Jaeger

Contact information

Type(s)
Scientific

Contact name
Dr Ralf Jaeger

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Increnovo 14-12 [BC30 Sports]

Study information

Scientific Title
Effects of co-administration of probiotic (Bacillus coagulans GBI-30, 6086) and protein (Casein) on markers of skeletal muscle damage, perceived recovery and athletic performance after an intense single leg training bout

Study objectives
To determine if the co-administration of GanedenBC30 with protein has a beneficial effect on muscle damage, recovery and athletic performance following a damaging exercise bout.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Florida Tampa institutional review board committee, 21/08/2014, ref: 18-25

Study design
Single-blind diet-controlled single-center crossover study.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Probiotic supplementation

Interventions
Healthy, recreationally trained male athletes consume 20g of casein (Control = CON) for 2 weeks (days 1-14), followed by a muscle-damaging exercise bout on day 15, perceptual measures on day 16 (24 hours post exercise), perceptual, muscle damage and performance measures on day 17 (48 hours post exercise), and perceptual measures on day 18 (72 hours post exercise). Following a one-week wash-out period (days 19-24), the athletes consume 20g of casein plus 1 billion CFU Bacillus coagulans GBI-30, 6086 (GanedenBC30; Ganeden Biotech Inc., Maryfield Heights, OH) for two weeks (days 25-38). A muscle-damaging exercise bout is then performed on day 39, perceptual measures on day 40 (24 hours post exercise), perceptual, muscle damage and performance measures on day 41 (48 hours post exercise), and perceptual measures on day 42 (72 hours post exercise). Both supplemental conditions are identical in appearance, taste, and weight.

Intervention Type
Supplement

Primary outcome measure
1. Perceptual measures of recovery [muscle soreness and perceived recovery] will be assessed using the visual analogue scale [VAS].
2. Markers of muscle damage determined:

2.1. Blood Creatine Kinase (CK)
2.2. Blood Urea Nitrogen (BUN)
2.3. Muscle Swelling (MS) will be assessed via two-dimensional, B-mode ultrasonography (GE, LoGIQ e) to determine muscle thickness of the vastus lateralis (VL)
3. Athletic Performance:
3.1. Single-Leg 1RM (1RM): will be assessed via one repetition maximum testing (1RM) in the one-legged leg press. Three maximal attempts will be allotted with the greatest 1 RM counting for final data.
3.2. Single-Leg Vertical Jump Peak Power (VJPP): will be assessed via maximal vertical jump peak power bout using a Tendo Unit (Trencin, Slovak Republic). Three maximal attempts will be allotted with the greatest peak power counting for final data. Participants will 60 seconds between vertical jump attempts.
3.3. Wingate Peak Power (WPP): will be assessed via Monark Wingate cycle ergometry (Monark™, Vansbro, Sweden). During the cycling test, the volunteer will be instructed to cycle against a predetermined resistance (7.5% of body mass) as fast as possible for 10 seconds.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2014

Completion date
09/05/2015

Eligibility

Key inclusion criteria
1. Normal, healthy individuals
2. Aged between 18-25 years
3. Recreationally Trained Males
4. Must be able to perform required testing

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
Male

Target number of participants
38

Total final enrolment
29

Key exclusion criteria
1. Subjects consuming any ergogenic sports nutrition supplements (incl. creatine, HMB, PA, ATP, carnitine or beta-alanine) at least 4 weeks prior to the beginning of the study.
2. Use of prescription medications (antibiotics, NSAIDs)
3. Use of probiotics or digestive enzymes
4. Smokers
5. Presence of any musculoskeletal, medical, or metabolic contraindications.

Date of first enrolment
23/02/2015

Date of final enrolment
16/03/2015

Locations

Countries of recruitment
United States of America

Study participating centre
Department of Health Sciences and Human Performance
The University of Tampa
401 W. Kennedy Blvd.
Tampa, Florida
United States of America
33606

Sponsor information

Organisation
Ganeden Biotech Inc.

Sponsor details
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44124

Sponsor type
Industry

Website
https://www.ganedenprobiotics.com

ROR
https://ror.org/05de34168

Funder(s)

Funder type
Industry

Funder Name
Ganeden Biotech Inc.

Results and Publications

Publication and dissemination plan
Plans to submit a publication to a peer-reviewed scientific journal in September 2015.

Intention to publish date
31/03/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Jacob M Wilson, Ph. D., jwilson@theaspi.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/07/2016	18/02/2019	Yes	No
Dataset		21/07/2016	10/10/2023	No	No