

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

<b>Submission date</b> 28/08/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input checked="" type="checkbox"/> Individual participant data
<b>Registration date</b> 07/09/2015	<b>Overall study status</b> Completed	
<b>Last Edited</b> 10/10/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## 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

**Contact details**

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United States of America

53202

## 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**

Suite 300

5800 Landerbrook Drive

Mayfield Heights

United States of America

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](mailto:jwilson@theaspi.com).

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	21/07/2016	18/02/2019	Yes	No
<a href="#">Dataset</a>		21/07/2016	10/10/2023	No	No