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Impact of brewer's yeast (beta-glucan supplementation) on body status and muscle damage after exercise stress

Submission date
01/04/2020

Recruitment status
No longer recruiting

Registration date
02/04/2020

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
Strenuous exercise has been shown to result in a temporary suppression of immune system activity. If this exercise-induced immunosuppression is continued at a high frequency, those engaging in regular strenuous exercise are at a higher risk for upper respiratory infections and other infections that may require a cessation of exercise or lead to reductions in overall performance. Exercising in the heat appears to exacerbate these physiological responses, in particular gastrointestinal distress, which encompasses a significant majority of immune cell activity.

Because of the apparent detrimental effects on immune system functioning following strenuous exercise, different strategies have been developed to attenuate these decrements in immune function. Specifically, different nutritional interventions and dietary supplement strategies have been utilized to serve as countermeasures. Beta-glucans may play a vital role in supporting innate immune system activity following strenuous exercise. Beta-glucans are a polysaccharide found within the cellular membranes of different plants, such as yeast, fungi and oats. Beta-glucan ingestion has been shown to enhance immune system activity following exercise; however, mixed results exist within the literature regarding the effectiveness of different types of beta-glucans and their ability to support immune function. Supplementation with beta-glucans derived from yeast may afford an improved level of protection from infection during periods of rigorous training. Therefore, the purpose of this study is to examine the efficacy of yeast-derived beta-glucan supplementation on reducing exercise-induced immunosuppression.

Who can participate?
Adults over 18 years, performing some form of aerobic exercise at least twice per week for the last 12 months and have a VO2Peak between the 50th and 80th percentile for their age and gender.

What does the study involve?
Participants will be randomly allocated to receive supplement of either 250 mg/day of yeast beta-glucan or a maltodextrin placebo for 13 days. Participants will arrive fasted and complete a

bout of treadmill exercise at 55% VO2Max in a hot and humid environment. Prior to and 0, 2, and 72 hours after completing exercise changes in white blood cell counts, pro- and anti-inflammatory cytokines, markers of muscle damage, markers of muscle function, soreness, and profile of mood states will be assessed.

What are the possible benefits and risks of participating?
The results of this study can be utilized to develop effective immune-boosting supplements to reduce exercise-induced damage and improve recovery from exercise and sport participation. Benefits can be translated to the general population.
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. Only personnel trained and cleared to perform blood sampling in research populations will perform the blood draws.
Yeast-derived beta-glucan utilized in this study is considered to be safe in long-term studies in a healthy human population.
Each exercise bout will consist of up to 60 minutes of treadmill running in a hot (35 – 40oC), humid (40 – 45%) environment. Throughout the exercise trial and to control for clinical safety while also standardizing physiological load, continuous core body temperature measurements will be made using orally ingested temperature sensors that communicate via a radio frequency to sensors integrated with software to measure core body temperature. Throughout each exercise bout, ab libutum water intake will be permitted.

Where is the study run from?
Lindenwood University (USA)

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

Who is funding the study?
Leiber GmbH (Germany)

Who is the main contact?
Prof Chad Kerksick, ckerksick@lindenwood.edu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LIN-INC-2018-0014

Study information

Scientific Title
The effect of yeast beta-glucan (Saccharomyces cerevisiae) supplementation on muscle damage, inflammatory markers, changes in mood and muscle function following a bout of treadmill exercise in a hot and humid environment

Study objectives
The purpose of this study was to examine the efficacy of yeast beta-glucan supplementation on reducing exercise-induced immunosuppression after an extended bout of treadmill exercise in a hot and humid environment for its ability to impact inflammation, muscle damage, muscle function, and mood state.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/06/2018, Lindenwood University IRB (Lindenwood University, 209 S Kingshighway St, St Charles, MO 63301, USA; +1 636-949-4730; IRB@lindenwood.edu), ref: 1242265-3

Study design
Interventional randomized double-blind crossover

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 contact details to request participant information sheet.

Health condition(s) or problem(s) studied
Recovery from stressful exercise

Interventions
Subjects will supplement with either 250 mg/day of yeast beta-glucan or a maltodextrin placebo for 13 days. Participants will arrive fasted and complete a bout of treadmill exercise at 55% VO2Max in a hot and humid environment. Prior to and 0, 2, and 72 hours after completing exercise changes in white blood cell counts, pro- and anti-inflammatory cytokines, markers of muscle damage, markers of muscle function, soreness, and profile of mood states will be assessed.

The order of supplementation (beta-glucan or placebo) was determined using http://www.randomizer.org/

Intervention Type
Supplement

Primary outcome measure
1. Indicators of muscle damage pre, immediately after, 2h and 72 hours post-exercise:
1.1. Perceived soreness measured using a 100-mm visual analog scale anchored with 0 – 'No Soreness At All' and 100-'Extreme, Debilitating Soreness'
1.2. Plasma creatine kinase measured using blood sample
1.3. Plasma myoglobin measured using blood sample
2. Cytokines (IL-1β, IL-6, IL-12, GM-CSF, TNF-α, IL-2, IL-7, IL-13, IFN-, IL-4, IL-8, IL-17, MCP-1, IL-6, IL-10, G-CST, and MIP-1β) measured using blood sample assay pre, immediately after, 2h and 72 hours post-exercise
3. Muscle function (maximal voluntary isometric contraction tests and a 50-repetition isokinetic muscle fatigue test): pre, immediately after, 2h and 72 hours post-exercise
4. Mood state measured using profile of mood states (POMS): pre, immediately after, 2h and 72 hours post-exercise
5. Indicators of physiological stress (heart rate, RPE, VO2, and core temperature values): up to 60 minutes or until reaching a core temperature of 39.2°C

Secondary outcome measures
Safety (Complete Blood Count and Comprehensive Metabolic Panel): pre, immediately after, 2h and 72 hours post-exercise

Overall study start date
01/11/2017

Completion date
03/08/2019

Eligibility

Key inclusion criteria
1. Performing some form of aerobic exercise at least twice per week for the last 12 months
2. Have a VO2Peak between the 50th and 80th percentile for their age and gender

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
31

Total final enrolment
31

Key exclusion criteria
1. Any individual who is currently being treated for or diagnosed with a cardiac, respiratory, circulatory, musculoskeletal, metabolic, immune, autoimmune, psychiatric, hematological, neurological or endocrinological disorder or disease.
2. Any individual being obese (defined as body mass index > 30 kg/m² and body fat greater than 30%)
3. Any female who is pregnant or breast-feeding
4. Any individual less than 18 and greater than 50 years of age

Date of first enrolment
21/06/2018

Date of final enrolment
01/08/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Lindenwood University
209 S. Kingshighway
St. Charles
United States of America
63301

Sponsor information

Organisation
Increnovo LLC

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Leiber GmbH

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
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article	19/04/2020	15/10/2020	Yes	No