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Effect of zinc carnosine and bovine colostrum, alone and in combination, on gut permeability following endurance exercise

Submission date
11/12/2014

Recruitment status
No longer recruiting

Registration date
03/02/2015

Overall study status
Completed

Last Edited
01/07/2016

Condition category
Other

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

Plain English summary of protocol

Background and study aims
One of the functions of the gut (intestine) is to act as a barrier to keep potentially harmful substances from entering the general circulation. It is normal, however, for it to be permeable to some substances – that is, let some nutrients pass though it into the circulation. During exercise, the blood supply to the gut is reduced and body temperature is increased. These are normal healthy responses to exercise but the bodily response can, at least in part, lead to a temporary dysfunction of the gut barrier, potentially causing substances that wouldn't normally be allowed to pass though. It has been suggested that this may be responsible for some of the gut complaints that are often reported during exercise. Because exercise can be easily controlled, it is a good model to study the effects of such stressors on gut permeability. There are a number of 'functional foods' or bioactive food products that can potentially improve (treat or prevent) gut injury and promote gastrointestinal health and repair in the event of gut injury. For example bovine colostrum has previously been shown to be beneficial in exercise studies. Zinc carnosine has also been shown to help reduce permeability of the gut caused by certain drugs (non-steroidal anti-inflammatory medications). However, these substances have been studied in isolation. In nature many bioactive substances actually work together and often in a synergistic (combined, multiplying effects) manner. Furthermore, a typical diet will involve many foods consumed in combination. Hence, it is important to study the interactions between bioactive foods. Early (preliminary) work has shown that combinations of nutrients positively influence gut protection and repair work synergistically in vitro (i.e. outside of the body, in laboratory 'test tube' type experiments). However, further research in this area is needed and application to an in vivo (in the body in a more 'real life') setting is desirable. Hence, the purpose of this study is to determine if zinc carnosine and bovine colostrum are more beneficial in combination that either alone.

Who can participate?
Healthy males aged between 18 – 45, at least recreationally active and familiar with running exercise. They should also be able to pass all pre-screening questions on the standard Physical Activity Readiness questionnaire.

What does the study involve?
Participants are randomly allocated into one of 4 groups. Those in group 1 are given a placebo twice a day. Those in group 2 are given zinc carnosine on its own twice a day. Those in group 3 are given bovine colostrum on its own twice a day. Those in group 4 are given both zinc carnosine and bovine colostrum twice a day. Each participant undergo 4 permeability assessments. Two of these are taken before the study begins when they are resting. A third assessment is made after the participant has run for 20 min on a treadmill (at 80% of their maximal aerobic capacity) 2 days after they have started taking the treatment. A final assessment is then made after the same type of exercise (20 min at 80% maximal aerobic capacity) 14 days after they have started treatment. There is then a 2 week washout period before the whole process is repeated and all participants take all 4 types of treatment. The permeability assessment simply requires drinking a solution containing a specific mix of sugars and then collecting all urine over the next 5 hours (permeability is assessed by the relative ratios of different sixed sugars in the urine sample). Blood samples are taken pre- and post-exercise.

What are the possible benefits and risks of participating?
Participants are not expected to receive any direct benefit. However, they are provided with a full report and feedback on their results and exercise data (e.g. VO2max). This feedback is similar to that which many fitness testing centres provide as a fee-paying service. Blood sampling carries a small risk of bruising or infection, but through safe and good procedures and good practice, any risk is minimal. All exercise is associated with increased risk of cardiac emergency. Since only healthy young participants are to be recruited, and all potential participants will be required to complete a Physical Activity Readiness Questionnaire (PAR-Q) prior to any exercise being performed this risk is minimal. Strenuous exercise can cause light headedness in some individuals but the previously noted screening will minimise this risk. If participants feel unwell at any time they are free to stop exercising should they wish to do so. Also, the proposed participant population should be familiar with the discomfort associated with strenuous exercise. The use of these supplements in this study poses no health risk and no serious side effects have been reported during or after use in healthy people. For bovine colostrum no side effects have been reported in many previous research studies but the occurrence of rare cases of minor side effects (i.e. minor rashes, bowel changes) are sometime reported. It is also a dairy product so is not suitable for dairy allergy or intolerance sufferers (who would be excluded from the study). If participants experience any gastrointestinal distress they will be asked to cease supplementation and withdrawn from the study. All procedures will be carried out by suitably trained and experienced staff, employing good practice and appropriate procedures to ensure any risk is minimal.

Where is the study run from?
Aberystwyth University (UK)

When is the study starting and how long is it expected to run for?
July 2012 to August 2013

Who is funding the study?
1. Aberystwyth University (UK)
2. University of Kent (UK)
3. Plymouth University (UK)

Who is the main contact?
Dr Glen Davison

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AberDSES_DSM1_Ex-perm-nutr_07-2010

Study information

Scientific Title
Effects of the nutriceuticals zinc carnosine and bovine colostrum, alone and in combination, on exercise induced increases in gut permeability, tight junctions, apoptosis and heat shock protein 70 production

Study objectives

1. Null: Zinc carnosine does not influence the exercise-induced increase in gut permeability
2. Null: Bovine colostrum does not influence the exercise-induced increase in gut permeability
3. Null: Zinc carnosine and bovine colostrum in combination does not influence the exercise-induced increase in gut permeability
4. Alternate: Zinc carnosine supplementation truncates the exercise-induced increase in gut permeability
5. Alternate: Bovine colostrum supplementation truncates the exercise-induced increase in gut permeability
6. Alternate: Zinc carnosine and bovine colostrum in combination truncates the exercise-induced increase in gut permeability to a greater extent than either alone (synergistic effects)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Aberystwyth University Ethics Committee for Research Procedures, July 2012

Study design
Single-centre interventional trial

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 a participant information sheet

Health condition(s) or problem(s) studied
Gut/intestinal permeability in healthy and physically active sports people

Interventions
The 4 experimental arms are as follows:
1. Placebo (twice per day: 10 g milk protein concentrate [total = 20 g/d] and 1 gelatin capsule containing 37.5 mg of microcrystalline cellulose [total = 75 mg/d])
2. Zinc carnosine alone (twice per day: 10 g milk protein concentrate [total = 20 g/d] and 1 gelatin capsule containing 37.5 mg of Zinc carnosine [total = 75 mg/d])
3. Bovine colostrum alone (twice per day: 10 g bovine colostrum powder [total = 20 g/d] and 1 gelatin capsule containing 37.5 mg of microcrystalline cellulose [total = 75 mg/d])
4. Zinc carnosine and bovine colostrum in combination (twice per day: 10 g bovine colostrum powder [total = 20 g/d] and 1 gelatin capsule containing 37.5 mg of Zinc carnosine [total = 75 mg /d])

Intervention Type
Supplement

Primary outcome measure
Gut permeability by urinary excreiton of non-matabolisable sugars (lactulose and rhamnose) over a 5 hour period (in which all urine is collected) after the oral ingestion of these test sugars.

Secondary outcome measures
Maximal oxygen consumption (VO2max); Core body temperature during exercise; Heart rate, subjective rating of perceived exertion, gas exchange (oxygen consumption and carbon dioxide output) during exercise; Full blood count, blood lactate, and blood glucose concentrations pre and post exercise trials (2 d and 14 d supplementation points in each arm).

Overall study start date
16/07/2012

Completion date
16/08/2013

Eligibility

Key inclusion criteria
1. Healthy adult (18 - 45 years), at least recreationally active and familiar with running exercise
2. Able to pass all pre-screening questions on standard Physical Activity Readiness questionnaire and hence lowest risk stratification (e.g. according to ACSM risk categories for physical exercise)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
8

Key exclusion criteria
1. Having a current infection (or had an infection in the 3 weeks prior to the study)
2. Exhibiting risk factors for cardiovascular (CV) conditions, metabolic or intestinal
3. Disorders
4. Smoking
5. Regular consumption of vitamin or sports supplements
6. Regular consumption of medication; regular alcohol intake over 2 units per day
7. Intolerance or allergy to milk (or dairy) products

8. Currently participating in another study (or within 3 weeks of completing one) having given blood in the 3 weeks prior to the study not habitually physically active
9. People who have other conditions known to alter intestinal permeability such as bowel surgery or caeliac disease

Date of first enrolment
09/07/2012

Date of final enrolment
19/04/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Aberystwyth University
Department of Sport and Exercise Science
Aberystwyth
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Sponsor information

Organisation
Aberystwyth University (UK)

Sponsor details
Research, Business & Innovation
Visualisation Centre
Penglais
Aberystwyth
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United Kingdom
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Sponsor type
University/education

ROR
https://ror.org/015m2p889

Funder(s)

Funder type
University/education

Funder Name
Aberystwyth University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
University of Kent

Alternative Name(s)
The University of Kent

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Plymouth University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
PhD thesis deposit in institutional repository by July 2015. Submission to peer reviewed journals by January 2015 (with actual publication intended for later in 2015).

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016		Yes	No