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Macronutrient ingestion, muscle glycogen and post-exercise recovery

Submission date
31/05/2011

Recruitment status
No longer recruiting

Registration date
28/06/2011

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Carbohydrates (commonly referred to as CHO) are the preferred substrate to support energy during prolonged moderate to high intensity exercise. In humans, the majority of CHO is stored as glycogen in the muscle and liver. However, these stores are finite and may become completely depleted with prolonged exercise. The importance of glycogen on endurance performance has been recognised for decades, and the ability to sustain exercise is closely related to pre-exercise glycogen availability in addition to the observation that fatigue often coincides with glycogen depletion.
Post-exercise nutrition has received less attention, although recovery is a critical part of training and is likely to affect the subsequent performance and health. A number of studies have showed that ingesting CHO would accelerate muscle glycogen. Other studies have showed that the addition of protein to CHO would result in even greater glycogen recovery. More research is needed to establish whether protein co-ingestion would improve glycogen restoration during short-term recovery and/or repeated exercise performance and whether glycogen availability could limit performance during repeated exercise.

Who can participate?
Healthy male participants who run regularly (2-4 hours/week) as part of their training and that are aged between 18 and 28 years old.

What does the study involve?
There will be two distinct phases of testing and two nutritional interventions will be compared in a cross-over study (i.e. participants will act as their own controls). There will be an interval of 21 days between the nutritional interventions. In phase I, participants will receive a solution containing either 3% or 12% CHO solution in equal volumes between treatments. In phase II, participants will receive either the same 12% CHO or an isoenergetic mixture of 8% CHO and 4% protein. Each participant will be required to undertake 2 preliminary tests and 2 main tests.
The first preliminary tests to be administered will last approximately 60-90 minutes and involve an assessment of running economy (called VO2 km-1) and maximal oxygen uptake (called VO2 max). A second preliminary test will take place on a separate day and participants will be asked to complete the exercise to be performed during the main tests but without any tissue samples being collected, in order to get used to the study procedures.

Each main test will involve a moderate to high intensity treadmill running until exhaustion before a 4 hour recovery period, during which participants will ingest one of the sports drinks every 30 minutes. Following recovery, participants will be asked to run on the treadmill until exhaustion. Venous blood and expired air samples will be collected throughout the trials. Heart rate will be monitored continually throughout the test. Muscle samples will be collected after each exercise session and following the intervening recovery. Brain wave (EEG) activity will be monitored during exercise by wearing a Lycra stretch cap with embedded electrodes. Participants will be required to weigh and record their normal food intake for 2 days during the preliminary test period and then adhere to this diet in the 2 days prior to subsequent main tests (scales and a food record diary will be provided). They will be required to arrive in the laboratory on the morning of each main test having observed a 10-12 hour fast. They will also need to refrain from heavy exercise, alcohol and caffeine in the 2 days prior to each main test.

What are the possible benefits and risks of participating?
During the VO2max and main tests, participants will be running to fatigue. But full recovery is expected within 5 minutes. Blood sampling may cause minor bruising and carries a small risk of air or plastic embolism, as can happen in such procedures, but good practice minimises any risks.

Where is the study run from?
All the tests will take place at the Physiology Research Laboratory at the University of Bath, UK.

When is the study starting and how long is it expected to run for?
The study is expected to start in June 2011 and complete in June 2013.

Who is funding the study?
The project is funded by the Saudi Arabian Ministry of Higher Education.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Macronutrient ingestion, muscle glycogen and post-exercise recovery: a randomised cross-over experimental design with two phases to examine the inter-relationships between ingesting various quantities of carbohydrate with and without added amino acids, muscle glycogen availability and the capacity to perform repeated bouts of exercise with limited recovery.

Study objectives
1. Muscle glycogen resynthesis and repeated exercise performance will present a dose-response relationship with the quantity of carbohydrate ingested
2. Muscle glycogen resynthesis will be similar between carobhydrate-protein and and energy matched carbohydrate supplements while repeated exercise performance will be improved with protein co-ingestion

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Service (NHS) South West 3 Research Ethics Committee (REC), 15/10/2009, ref: 09/h0101/82

Study design
Randomised double blinded cross-over experimental study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Nutrition and post-exercise recovery

Interventions
1. Provision of different nutritional supplements during a 4 hour recovery period and the assessment of exercise capacity following recovery phase
2. There are 4 treatment arms (2 in each phase)
3. The total number of participants would be 10 in phase I and 10 in Phase II in a crossover experimental design
4. Thus, in each phase the same participants (n=10) will undergo both treatment arms
5. Phase I will include comparisons of recovery and subsequent performance between a high CHO (1.2 g.kg BM) vs low CHO (0.3 g.kg BM) supplements provided in 7 doses at a 30 minute intake interval during recovery
6. Phase II will include comparisons of recovery and subsequent performance between a CHO-protein (0.8 g.kg BM CHO + 0.4 g.kg BM
7. Protein vs an isoenergetic CHO supplement (1.2 g.kg BM) provided in 7 doses at a 30 minute intake interval during recovery

Intervention Type
Supplement

Primary outcome measure
1. Muscle glycogen resynthesis rates and repeated running capacity following short-term recovery.
2. For muscle glycogen measurement, muscle samples from the thigh will be obtained via needle biopsy technique
3. For measurement of repeated running capacity, a run time to volitional exhaustion at 70% VO2max will be employed
4. All measurements contributing to both the primary and secondary outcomes are made throughout two 7 hour (approximate) lab visits in each phase of the study

Secondary outcome measures
1. All the mechanistic data explaining how the interventions may have impacted on both the restoration of glycogen stores and attenuation of the onset of fatigue during a subsequent exercise bout (metabolic regulatory hormones, blood and plasma metabolites, brain wave function and estimation of extramuscular carbohydrate oxidation)
2. For the determination of metabolites in the blood, venous blood samples will be drawn via an indwelling catheter fitted to an antecubital vein during exercise and recovery
3. For estimation of extramuscular CHO oxidation will be calculated as the difference between whole-body CHO oxidation through Douglas bag method (derived from indirect calorimetry) and the rate of intramuscular CHO oxidation (estimated from glycogen degradation)
4. For Measurement of brain wave activity, an EEG-specific Lycra stretch head cap with imbedded electrodes will be worn by participants
5. All measurements contributing to both the primary and secondary outcomes are made throughout two 7 hour (approximate) lab visits in each phase of the study

Overall study start date
17/06/2011

Completion date
17/06/2013

Eligibility

Key inclusion criteria
1. Healthy male participants
2. Habitually active with running as a central component of their training (2-4 hours/week)
3. Aged between 18-28

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
28 Years

Sex
Male

Target number of participants
20

Key exclusion criteria
1. Participation in any other clinical trial
2. Any known bleeding or metabolic disorders
3. Any known allergies towards stitches
4. Any reported use of substances that may be deemed as a risk to the person or the experiment
5. Any other condition or behaviour that may be deemed as a risk to the person or the experiment

Date of first enrolment
17/06/2011

Date of final enrolment
17/06/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Bath
Bath
United Kingdom
BA2 7AY

Sponsor information

Organisation
Saudi Arabian Ministry of Higher Education (Saudi Arabia)

Sponsor details
Royal Embassy of Saudi Arabia
Cultural Bureau in London
630 Chiswick High Road
London
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W4 5RY

Sponsor type
Government

Website
http://www.mohe.gov.sa/en/studyinside/aboutKSA/Pages/default.aspx

ROR
https://ror.org/00q919b81

Funder(s)

Funder type
Government

Funder Name
Saudi Arabian Ministry of Higher Education (Saudi Arabia) (ref: s4305)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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?
Protocol article	protocol	26/03/2014		Yes	No
Results article	results	01/01/2016		Yes	No