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PEPTIDE (Post-Exercise Protein Trial: Interactions between Diet and Endurance)

Submission date
13/11/2013

Recruitment status
No longer recruiting

Registration date
04/12/2013

Overall study status
Completed

Last Edited
23/10/2018

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
Regular exercise has many benefits to health. These benefits are usually the result of adaptations in the heart, lungs, vasculature and muscles in response to exercise. As a result, endurance capacity to perform daily work tasks is improved by better oxygen delivery to the working muscles. Recently, it was shown that nutrition can have an impact on how the body adapts from a single exercise session. This led to the current interest in nutrition and adaptations from exercise in longer periods of exercise training.
Post-exercise nutrition is an important part of recovery, and to prepare for the next training session. However, the long-term effect of nutrition after exercise requires further investigation. It is possible that the addition of protein and/or carbohydrate can further improve aerobic training adaptations that can lead to greater health and fitness outcomes. The aim of the study is to investigate the role of post-exercise nutrition in improving endurance training adaptations, and whether the timing of ingestion would affect this response.

Who can participate?
Healthy males and females aged between 18-48 years old.

What does the study involve?
There will be two distinct phases. In Phase I, participants will be randomly assigned to either a carbohydrate-alone (standard control) or a carbohydrate-protein group. During Phase II, both groups will take the carbohydrate-protein supplements but the timing of ingestion will be either immediately post-exercise or during an overnight recovery period. The training intervention will be identical for all groups. The only difference will be the timing/type of supplements ingested following each exercise session. Participants will be asked to complete two baseline visits before they start 6-weeks of endurance training. After the training period, they will be asked to complete follow-up measurements (same measurements as the 2 baseline visits). The baseline and follow-up measurements will include measurements of running economy, maximal oxygen uptake (VO2 max), body and fat mass on the first visit. The second visit will include collection of expired gas, venous blood and muscle samples.
The training intervention will be a 6-week endurance training that involves treadmill running for 4 days/week. A progressive increase in exercise duration and intensity will be applied. The duration of exercise sessions will gradually increase from 30-60 minutes from week 1 to week 6

of training, while the intensity of exercise will increase from 70% to 75% of VO2 max. Participants will be given access to the treadmills at the Sports training Village at the University of Bath to undertake the training programme.

What are the possible benefits and risks of participating?
Participants will benefit from a structured 6-week exercise programme, while receiving nutritional supplements to support the training demands. Detailed analysis of dietary food intake, accurate measurement of aerobic fitness and personalised data describing how each participant responded to training/treatments will be provided. Finally, a 6-month free gym membership at the Sports Training Village (University of Bath) will be given to participants who successfully adhere and complete the study.
Muscle biopsies are common in exercise studies. The only minor complications are typically observed (e.g. bleeding from the skin wound, bruising and minor soreness over the days afterwards). Participants are provided with an extensive guide (included with the participant information sheet) to help manage these issues. The use of anaesthetic for muscle biopsies may cause possible side effects including allergic reactions and nausea. However, the initial health screen will be individually checked by a doctor who will sign a Patient Specific Direction (PSD) to prescribe the anaesthetic for the procedure. Blood sampling may cause minor bruising and carries a very small risk of infection as can happen in such procedures, but strict adherence to best practice minimises any risks. During the VO2 max test, participants will be running to fatigue. But full recovery is expected within 5 minutes.
Physical exercise increases the risk of certain adverse events (e.g. musculoskeletal injury) but other risk factors will be screened before participants take part in any exercise.

Where is the study run from?
The baseline and follow-up measurements will take place at the Physiology Laboratory at the University of Bath. The 6-week training will be at the Sports Training Village, University of Bath.

When is the study starting and how long is it expected to run for?
The study is expected to start in November 2013 and complete in January 2015.

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
Examining the role of post-exercise nutrient composition and timing in modulating the adaptive response to endurance training

Acronym
PEPTIDE

Study objectives
1. Protein feeding following regular exercise leads to improved cardiovascular and intramuscular endurance training adaptations.
2. Immediate post-exercise protein feeding will increase the magnitude of cardiovascular and intramuscular endurance training adaptations relative to an isocaloric and isonitrogenous overnight protein feeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Service (NHS) South West 3 Research Ethics Committee (REC), 04 November 2013, Ref: 13/SW/0239

Study design
Randomised double blinded independent-group experimental study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Nutrition and exercise training adaptations

Interventions
The study will involve two phases of testing with the provision of different nutritional supplements following exercise and the determination of endurance training adaptations in response to 6 weeks of training.

Participants recruited for Phase I (35 participants) of testing will receive a supplement containing either 4 % carbohydrate (sucrose) plus 4% protein or 8% isocaloric carbohydrate.

The two nutritional interventions provided in Phase II (35 participants) will be identical (i.e. 4 % carbohydrate plus 4% protein) while the timing of intake will be manipulated. A group will ingest the supplement immediately post-exercise and one hour later, while the overnight recovery group will receive the supplements one hour prior to sleep and at 02:00 am as an overnight nutritional intervention.

The intervention will be 8 weeks and will consist of a baseline testing week with 2 exercise sessions, six weeks of treadmill endurance exercise and a final week of follow-up measurements.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Indications of endurance training adaptations on whole-body (via measurements of maximal oxygen uptake and haematologic parameters) and tissue specific levels (via muscle biopsies) following 6 weeks of endurance exercise training with each nutritional treatment.

Secondary outcome measures
No secondary outcome measures

Overall study start date
18/11/2013

Completion date
30/01/2015

Eligibility

Key inclusion criteria

1. Both males and females.
2. Aged between 18-48.
3. Individuals free from cardiovascular, metabolic or joint disease as determined by standard health questionnaire.
4. Nonsmoker.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
48 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Known or suspected food intolerances, allergies or hypersensitivity.
2. Any bleeding disorder or taking medication which impacts blood coagulation.
3. Known tendency towards keloid scarring.
4. Known sensitivity or allergy to any local anaesthetic medicines.
5. Any reported use of substances which may pose undue personal risk to participants or introduce bias into the experiment.
6. Any other condition or behaviour deemed either to pose undue personal risk to participants or introduce bias into the experiment.

Date of first enrolment
18/11/2013

Date of final enrolment
30/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department for Health
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
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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	24/11/2014		Yes	No
Results article	results	23/02/2018		Yes	No
HRA research summary			28/06/2023	No	No