The effect of oral capsinoids supplementation on exercise-induced fatigue and molecular biomarkers involved in skeletal muscle fuel recovery in humans

| Submission date 31/07/2019 | Recruitment status No longer recruiting | Prospectively registeredProtocol |
|-------------------------------------|---|--|
| Registration date 07/08/2019 | Overall study status Completed | Statistical analysis plan Results |
| Last Edited 16/08/2019 | Condition category Other | Individual participant data Record updated in last year |

Plain English summary of protocol

Background and study aims

Capsinoids (CSN), the novel non-pungent capsaicin analogs reported to promote metabolic health and exercise tolerance. Previous literature revealed that capsinoids administration could enhance fat oxidation, as well as suppress the body fat accumulation in humans. However, the vital molecular mechanism remains under investigation, as CSN considering as an ergogenic aid to enhance fat oxidation and energy restore. This study investigated the effect of post-exercise CSN supplementation on energy reliance, muscle glycogen resynthesis and changes in GLUT4 and p-Akt/Akt protein expressions in the skeletal muscle of young adults, during recovery.

Who can participate?

Nine healthy adult male volunteers (aged 21.4±0.2 years, height 171.8±1.8 cm, weight 64.9±4.3 kg, BMI 21.9±1.3 kg / m2, VO2max 47.1±1.8 ml/kg/min) of the Department of Physical Education, National Taichung University of Education participated in this study.

What does the study involve?

All subjects performed a crossover study and randomized to capsinoids and placebo trials. Participants undergo a cycling exercise challenge, muscle biopsied, blood and gaseous samples collect for analysis of metabolism, with a maximum interval from the beginning to the end of tests of two days.

What are the possible benefits and risks of participating?

The benefits for participants are to understand their own data related exercise physiology measurements and improve individual currently existing knowledge in the field of sports physiology. However, there were no possible risks existing in this experimental process because previous results have been published in SCI Journals using similar study design and experimental process.

Where is the study run from? National Taichung University of Education.

When is the study starting and how long is it expected to run for? August 2016 to January 2017

Who is funding the study? Ministry of Science and Technology in Taiwan.

Who is the main contact? Professor I-Shiung Cheng ischeng1965@mail.ntcu.edu.tw

Contact information

Type(s) Scientific

Contact name Prof I-Shiung Cheng

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers CCH IRB No. : 131233

Study information

Scientific Title

Fffect of acute post-exercise capsinoids supplementation on energy substrate utilization in young adults

Acronym

N/A

Study objectives

We hypothesized that oral CSN supplementation immediately after exercise may increase the fat oxidation and whole-body insulin sensitivity resulting as to replenish the muscle glycogen levels during post-exercise recovery. Therefore, we measured the glycogen concentration, GLUT4 expression, glucose/insulin, and gaseous exchange data to explore the evidence that post-exercise CSN supplementation could alter energy reliance and enhance glycogen content in skeletal muscle of young men.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/03/2016, the Ethics Committee and Institutional Review Board (IRB) of Changhua Christian Hospital (50006 No. 20 Jianbao Street, Changhua City, Taiwan; d9065@cch.org.tw; +886-4-7238595), ref: CCH IRB No.131233.

Study design Randomised cross-over trial

Primary study design Interventional

Secondary study design Randomised cross over trial

Study setting(s) School

Study type(s) Treatment

Participant information sheet See additional files (Chinese)

Health condition(s) or problem(s) studied

All participants in this study were non-alcoholics and non-smokers with a stable medical condition. To avoid the influence of other factors on results, participants were instructed to have a balanced diet and healthy lifestyle. In addition, the consumption of caffeine, tea, and tobacco was strictly prohibited during the experimental period.

Interventions

Participants in this crossover designed study were randomly assigned into two trials, including placebo and CSN (capsinoids).

All participants performed a 60-min cycling exercise on an ergometer at 70% VO2max. While performing the exercise and during recovery, participants had free access to drinking water. Then, immediately after a 60-min exercise, subjects ingested with CSN or placebo capsules (12 mg) and a high-carbohydrate meal within 10-min. Each meal consisted of 80% carbohydrate (2 g /kg body weight), 8% fat, 12% protein, and overall GI was 76.6 with an average weight of 184±7 g. The items in carbohydrate meal include corn flakes (Kellogg's Ltd, Manchester, UK), skimmed milk, white bread, strawberry jam, glucose water, and water.

Muscle biopsies were performed immediately (0h) and 3h after exercise, and collected vastus lateralis muscle samples were stored at -80°C for further analyses. Simultaneously, blood and gaseous samples were collected before, immediately after exercise (0h) and during the 3h post-exercise recovery period.

We choose the dose of 12 mg of CSN as an oral supplement, which is also a similar dosage to the human study of Josse and colleagues. The CSN capsules were purchased from the Ajinomoto Co Inc (Ajinomoto, Tokyo, Japan).

The same trial was repeated following the 2-week washout interval with the same dose of CSN and placebo capsules.

Intervention Type

Supplement

Primary outcome measure

 Glycogen levels in biopsied skeletal muscles are measured using an aseptic technique, an incision (10 mm length and depth) was made in the skin and muscle fascia at about 20 cm above the knee of the right leg at 0-h (immediately after exercise) and 3-h after exercise.
 Fat oxidation rate in a gaseous sample is measured using MetaMax3B indirect calorimetry (Cortex Biophysik, Nonnenstrasse, Leipzing, Germany) to collect individual's gaseous samples at every 60-min during 3h post-exercise recovery i.e., at 60, 120 and 180-min after exercise for both trials.

Secondary outcome measures

1. p-Akt/Akt ratio is measured using Western blot in muscle biopsied samples at 0-h and 3-h after exercise.

2. GLUT4 expression using Western blot in muscle samples at 0-h and 3-h after exercise.

3. Blood glucose is measured using an automated glucose analyzer supplied by YSI Life Sciences (Yellow Springs, OH, USA) at every 30-min during 3h post-exercise recovery.

4. Insulin is measured using commercially available kits (Randox, Antrim, UK) on an automated analyzer (Hitachi 7020, Tokyo, Japan). at every 30-min during 3h post-exercise recovery.

5. NEFA is measured using commercially available kits (Randox, Antrim, UK) on an automated analyzer (Hitachi 7020, Tokyo, Japan). at every 30-min during 3h post-exercise recovery.

6. Glycerol concentrations are measured using commercially available kits (Randox, Antrim, UK) on an automated analyzer (Hitachi 7020, Tokyo, Japan). at every 30-min during 3h post-exercise recovery.

Overall study start date

31/12/2015

Completion date 16/04/2017

Eligibility

Key inclusion criteria

- 1. Healthy male college student.
- 2. Non-alcoholic.
- 3. Non-smoker.
- 4. Stable medical condition.

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Male

Target number of participants 9

Key exclusion criteria

1. Can't follow the suggestions of a balanced diet 3 days before the experimental process.

2. Consume caffeine, tea, and tobacco and can't be strictly prohibited during the experimental period.

3. Can't tolerance the cycling exercise challenge including VO2max test and completed a 60-min cycling exercise at 70% VO2max.

Date of first enrolment

15/04/2016

Date of final enrolment 15/05/2016

Locations

Countries of recruitment Taiwan

Study participating centre National Taichung University of Education No 140 Minsheng Road, West Dist, Taichung City, Taiwan Taichung Taiwan 40306

Sponsor information

Organisation Ministry of Science and Technology

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Sponsor type Government

Website http//www.most.gov.tw

ROR https://ror.org/02kv4zf79

Funder(s)

Funder type Government

Funder Name Ministry of Science and Technology, Taiwan

Alternative Name(s) Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type Government organisation

Funding Body Subtype National government

Location Taiwan

Results and Publications

Publication and dissemination plan

Planned publication in the PLOS ONE Journal.

Intention to publish date

30/08/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|------------|--------------|------------|----------------|-----------------|
| Participant information sheet | version v1 | 05/08/2019 | 16/08/2019 | No | Yes |