Creatine monohydrate supplementation in young, healthy vegetarian adults and its effect on brown adipose tissue activation

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The main objective of this study is to determine whether creatine monohydrate supplementation enhances diet-induced thermogenesis and brown adipose tissue activity in young, healthy adults, as quantified through PET-MR, following an acute cold...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46813

Source
ToetsingOnline

Brief title
Crea-BAT

Condition

- Other condition

Synonym
Metabolism

Health condition

energiemetabolisme

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brown adipose tissue, Creatine, Diet-induced thermogenesis

Outcome measures

Primary outcome

SUVmean and SUVmax of brown adipose tissue depots as determined by PET-MR using

the 18F-FDG tracer.

Secondary outcome

- Diet-induced thermogenesis;

- Ex vivo mitochondrial respiration in skeletal muscle;

- In vivo mitochondrial function in skeletal muscle

- Blood and muscle creatine;

- Blood metabolites;

- Body composition;

- Metabolic substrate handling;

- Molecular pathways and gene transcription putatively responsible for

triggering improved mitochondrial health and function.

Study description

Background summary

Pre-clinical studies indicate that creatine may play a substantial role in

diet-induced thermogenesis and may have a profound effect on energy balance. A recent retrospective study of BAT activation on PET-CT scans in humans showed a positive association with the estimated renal creatinine clearance and BAT activation, possibly linking creatine metabolism in humans to BAT activity. In humans, so far little options are available to activate brown adipose tissue. The most important intervention to activate BAT is via cold, which has previously been shown to have metabolic effects in humans. Provided the potential health benefits of brown adipose tissue activation in humans, and provided the role of brown fat in diet induced thermogenesis, we here aim to determine whether creatine monohydrate supplementation can increase diet-induced thermogenesis and activate brown adipose tissue in humans.

Study objective

The main objective of this study is to determine whether creatine monohydrate supplementation enhances diet-induced thermogenesis and brown adipose tissue activity in young, healthy adults, as quantified through PET-MR, following an acute cold exposure.

Study design

A double-blind, randomised, controlled, cross-over intervention trial, in which creatine monohydrate supplementation will be compared to placebo.

Intervention

Creatine monohydrate will be supplemented at 5 grams four times daily.

Study burden and risks

This study will lead to novel insights with respect to the effect of creatine monohydrate on diet-induced thermogenesis and the activation of brown adipose tissue in humans. However, this study is not expected to be directly beneficial to the participants. The major burden to the subjects is a time investment. Subjects will be asked to attend the university on, in total, 7 occasions for measurement procedures. Additionally, subjects will be asked to consume creatine monohydrate versus placebo on a daily basis for a period of 9 days each. The experimental procedures are without risks, except for blood sampling and sampling of muscle and white adipose tissue biopsies, which can occasionally cause a local hematoma or bruising. The risk of infection or prolonged bleeding is low due to state of the art techniques and sterility measures. Measurements performed during the time course of the study can potentially lead to coincidental medical findings. Subjects will be informed about such a finding and possibly be advised to contact their own physician about this.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male or female;
- Caucasian;
- 18 to 30 years of age;
- Consuming a vegetarian diet;
- BMI 20-25 kg/m2.

Exclusion criteria

- Not meeting all inclusion criteria;
- Non-vegetarian diet;
- Excessive alcohol and/or drug abuse;

- Significant allergies or intolerances concerning the study products;
- Participation in another biomedical study within 1 month before the first study visit, possibly interfering with the study results;
- Medication use known to hamper subject*s safety during the study procedures; *
- Subjects with contra-indications for MRI and/or PET-CT;
- Subjects who do not want to be informed about unexpected medical findings; *
- Subjects who do not want that their treating physician to be informed;
- Co-morbidities to which the intervention or program that may pose as a complicating factor;
- Inability to participate and/or complete the required measurements;
- PET-CT scan in the preceding year.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2018
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO

Date:	28-03-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	04-07-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL64709.068.18
Other	volgt z.s.m.