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Metabolic effects of mustard

Submission date	Recruitment status	[_] Prospectively registered
03/07/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/07/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/08/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Increasing energy use (energy expenditure) is a way for overweight or obese people to lose weight. Mustard's pungent component AITC has the potential to increase energy expenditure and may have other beneficial effects on metabolism. The aim of this study is to investigate the effects of mustard on energy expenditure, glucose and fat utilization, body temperature, cold and hunger scores and blood values such as glucose.

Who can participate?
Healthy volunteers aged 18 to 65

What does the study involve?
Participants are studied on three different days. On each day they take either a spoon of mustard or capsulated mustard, or capsules with a placebo (dummy) mixture. At 30-minute intervals indirect calorimetry (a way to measure energy expenditure and fat and glucose utilization), cold/hunger scores and blood tests are performed. Temperature is measured continuously using a temperature monitoring pill. In between the measurements participants are allowed to read or watch TV but confined to bed. Blood samples are taken via an venous catheter (tube into a vein). Afterwards they eat a test meal during which appetite and food intake are measured.

What are the possible benefits and risks of participating?
There were no specific risks or benefits for the volunteers from participating in the study. Volunteers are reimbursed for travelling expenses and offered compensation for time spent participating.

Where is the study run from?
University of Cambridge Metabolic Research Laboratories, Wellcome Trust-MRC, Institute of Metabolic Science, Addenbrooke's Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2012 to January 2014

Who is funding the study?
The trial was funded by grants from the NIHR, BRC Seed Fund, Marie Curie Fellowships, Welcome Trust Fellowship, MRC, BHF and the BBSRC

Who is the main contact?
Dr M Langeveld

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Mustard1

Study information

Scientific Title
Metabolic effects of mustard allyl-isothiocyanate compared to placebo: a randomised cross over trial

Study objectives
Ingestion of mustard (containing the active ingrediënt allyl-isothiocyanate (AITC)) induces thermogenesis (primary outcome) and alters body temperature, cold and hunger sensations, plasma metabolic parameters and energy intake (secondary outcomes).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge Central East of England Research Ethics Committee, 22/03/2012, ref: 6/Q0108/84

Study design
Randomised cross over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Overweight, obesity

Interventions
In this study with a crossover design, 10 healthy subjects were studied under temperature controlled conditions after an overnight fast. After the ingestion of capsulated mustard (10 grams) or unpackaged mustard (10 grams) or capsulated placebo mixture, measurements of energy expenditure, substrate oxidation, core temperature, cold and hunger scores and plasma parameters were repeated every 30 minutes during 150 minutes. Randomisation was done by flipping a coin by the investigator to decide between the administration of capsulated mustard or the administration of capsulated placebo mixture. Unpackaged mustard was given as final intervention since participants could not be blinded to this intervention. After the experiments were performed, energy intake was measured in a test meal using the universal eating monitor.

Intervention Type
Supplement

Primary outcome(s)
Energy expenditure (thermogenesis), measured using by indirect calorimetry using a ventilated canopy respiratory gas exchange (GEM; GEMNutrition, Daresbury, UK) at baseline and 30, 60, 90, 120 and 150 minutes after the intervention

Key secondary outcome(s))
Measured at baseline and 30, 60, 90, 120 and 150 minutes after the intervention:
1. Core body temperature, measured using a temperature pill (VitalSense, Respironics, Bend, OR, USA)
2. Cold and hunger sensations, determined by asking the participant to rate the sensation of cold of the whole body and hands separately on a 1 to 10 scale, with ratings as following; 1 was rated as not at all cold and 10 was the coldest one had ever felt. Similarly for the degree of hunger, with ratings as: 1 for not hungry at all, and 10 was rated as the most hungry one had ever felt
3. Plasma metabolic parameters; blood samples taken via an indwelling venous catheter
3.1. Glucose measured using the Hexokinase method on a Siemens Dimension RXL AutoAnalyser, reagents and calibrators purchased from Siemens
3.2. Non-esterified free fatty acids (NEFAs) measured using the Roche Free Fatty Acid kit
3.3. Free thyroxin (fT4) measured by time-resolved fluorescence immunoassay on an AutoDELFIA analyser (Perkin Elmer) using kits from Perkin Elmer
3.4. Cortisol measured by fluorescence immunoassay on the Siemens Centaur Autoanalyser
4. Energy intake determined by using the Universal Eating Monitors (UEM)(The Sussex Meal Patterning System) during the test meal at 160 minutes after the intervention. Subjects ate a homogenous test meal (e.g. pasta) containing normal energy percent ratios (~30% carbohydrates, ~30% protein and ~40% fat). Test meal intake continuously monitored using the UEM equipment

Completion date
03/01/2014

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. Men and women
3. Non-smokers
4. Age between 17 and 65 years
5. No known medical conditions
6. Not taking any medications or supplements likely to influence energy expenditure

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Known medical conditions
2. Using medication or supplements likely to influence energy expenditure or other metabolic parameters

Date of first enrolment
01/04/2012

Date of final enrolment
19/11/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Cambridge Metabolic Research Laboratories, Wellcome Trust-MRC, Institute of Metabolic Science, Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Institute of Metabolic Science

ROR
https://ror.org/0264dxb48

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
BRC Seed Fund

Funder Name
FP7 People: Marie-Curie Actions

Alternative Name(s)
PEOPLE - Specific Programme 'People' Implementing the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007 to 2013), FP7 Specific Programme 'People' Implementing the Seventh Framework Programme of the European Community for Research, Technological Development and

Demonstration Activities (2007 to 2013), Specific Programme 'People' Implementing the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007 to 2013)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
British Heart Foundation

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Biotechnology and Biological Sciences Research Council

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, Agricultural and Food Research Council, Biotechnology & Biological Sciences Research Council, BBSRC, BBSRC UK, AFRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as this was not outlined in the original study set up and application to the medical ethics committee. The original data will be held at the University of Cambridge Metabolic Research Laboratories, Wellcome Trust-MRC, Institute of Metabolic Science, Addenbrookes Hospital.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2017		Yes	No