ISRCTN13980309 https://doi.org/10.1186/ISRCTN13980309

Capsaicinoids Enhance Metabolic Rate – An Open Label Study

Submission date	Recruitment status	[_] Prospectively registered
08/12/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/12/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/07/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Obesity is a growing problem worldwide. The main reason that people become obese is thought to be due to over-eating and/or not exercising enough. It has also been found that some people with obesity have a lower metabolism than healthy people. Capsaicinoids are a type of chemical which are found in members of the capsicum family of plants (chilies). There is evidence to suggest that capsaicinoids may play a role in metabolism (the breakdown of food and drink into energy). The aim of this study is to look at the effect of capsaicinoids on metabolism for weight management.

Who can participate?
Healthy adults who have a sedentary or lightly active lifestyle.

What does the study involve?
Participants are randomly allocated to one of two group who receive two treatments in a random order, with one week of no treatment in between. The first treatment involved receiving 100mg Capsimax (Capsaicinoids 2 mg) with a meal. The second treatment involves receiving a placebo (dummy drug) with a meal. Before and then 1, 2 and 3 hours after consuming the meal, participants have their metabolic rate calculated using specialized equipment and their heart rate measured. In addition, participants are asked to rate their appetite and interest in eating after 3 hours.

What are the possible benefits and risks of participating?
Participants benefit from learning about their own energy expenditure (metabolism). There are no known risks involved with participating.

Where is the study run from?
Arizona State University (USA)

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

Who is funding the study?
OmniActive Health Technologies Ltd. (India)

Who is the main contact?
Dr Vijaya Juturu
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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
STUDY00004264

Study information

Scientific Title
Capsaicinoids Enhance Metabolic Rate Using a Novel Metabolic Tracker Breezing Device – An Open Label Study

Study objectives
The digestion of the meal induce energy expenditure processes that produces heat, increases heart rate due to higher blood circulation, and increases oxygen consumption and carbon dioxide production. The latter is measured via breath analysis and a measurement named metabolic rate or energy expenditure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Arizona State University- Enterprise and Development IRB, 28/04/2016

Study design
Single blind acute placebo-controlled crossover open label study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
School

Study type(s)
Prevention

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
Metabolism

Interventions
Participants are randomised to one of two groups who receive two treatments in a random order.

Group 1: Participants receive 100 mg Capsimax (Capsaicinoids 2 mg) once a day with a meal single administration..
Group 2: Participants receive a placebo (corn starch) once a day with a meal single administration.

After each treatment period, participants undergo one week wash-out before starting the other treatment.

The Breezing® device evaluates people’s energy expenditure (EE) by detecting the rate of oxygen consumption and carbon dioxide generation in breath. It is based on a flow meter for flow detection and a chemical sensing cartridge, which used a cell-phone camera for optical detection. The device is 6.0 oz. (170 g), and 1.8 in × 2.1 in × 4.8 in (4.7 cm × 5.4 cm × 12.3 cm), and connects wirelessly to an iOS/Android mobile device, via Bluetooth®. A QR code with pre-calibrated sensor information is applied on the single-use sensor cartridge, which can be scanned and recognized by the mobile application.
During each measurement, participants breathed through a disposable mouthpiece connected to the Breezing® device for about 1-2 minutes until a total of 6L exhaled breath were measured by the flow meter. The data received on the mobile device is processed and displayed on the application. According to Weir equation, RQ, VO2 and VCO2, the energy expenditure is

determined. The participants will be provided with meal including a non-caloric, decaf drink and certain amount of Thomas Plain Bagel and 1/3 less fat Philadelphia cream cheese based on their REE level. The ratio of calorie intake to their REE value was 0.35 for 14 participants and 0.25 for 25 participants. In the meantime, the participants will be served with either a Capsaicinoids pill or a placebo pill. After finishing the meal/pill, the participants' metabolic rate will be measured at 1, 2, and 3 hours .

Intervention Type
Supplement

Primary outcome measure
Resting Energy Expenditure (Metabolic rate) is measured using breezing equipment (indirect calorimetry) at baseline, 1 hour, 2 hours and 3 hours and data calculated for 24 hours (overall average ΔREE%).

ΔREE: REEi – REE0
ΔREE (%) : [(REEi – REE0)/REE0] *100%

Secondary outcome measures
1. Heart rate measured using i-phone apps and blood pressure are measured using with sphygmomanometer at baseline and after 3 hours
2. Appetite and interest on food intake is measured using a visual analogue scale (0-100 scale) at baseline and at 3 hours

Overall study start date
01/05/2016

Completion date
15/12/2016

Eligibility

Key inclusion criteria
1. English-speaking
2. Adult participants (18 – 80 years old)
3. Sedentary or lightly active lifestyle
4. Able to consent and perform the necessary tests for the study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 subjects Crossover trial

Key exclusion criteria
1. Food allergy or sensitive to gluten
2. Under treatment for chronic conditions/disease such as cancer, burns or obstructive pulmonary diseases

Date of first enrolment
10/05/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Arizona State University
Center of Bioelectronics and Biosensors
Biodesign Institute
Tempe AZ
United States of America
85281

Sponsor information

Organisation
OmniActive Health Technologies Ltd.

Sponsor details
Phoenix House, T- 8, A Wing
462 Senapati Bapat Marg, Lower Parel
Mumbai
India
400 013

Sponsor type
Industry

Website
http://omniactives.com/

ROR
https://ror.org/03fxrgb29

Funder(s)

Funder type
Industry

Funder Name
OmniActive Health Technologies

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Erica Forzani (eforzani@asu.edu) or Dr Vijaya Jutruu (v. juturu@omniactives.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/06/2017		Yes	No