ISRCTN16751129 https://doi.org/10.1186/ISRCTN16751129

Capsaicinoids effect on appetite response

Submission date
16/12/2016

Recruitment status
No longer recruiting

Registration date
24/01/2017

Overall study status
Completed

Last Edited
31/07/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Obesity is a growing problem worldwide, which puts people at risk of developing serious health problems such as diabetes and heart disease. Capsaicinoids are compounds which are found in peppers. The most common of which is capsicum, which is an important component of chili peppers. Studies have shown that consuming capsaicinoids may help boost metabolism, which could help people to lose weight. The aim of this study is to look at the effects on the body of taking capsaicinoid-containing supplements for a week with breakfast.

Who can participate?
Adults aged between 19 and 51 years who are overweight or obese.

What does the study involve?
All participants are given 100 mg Capsimax (which contains capsaicinoids) to take by mouth with their breakfast meal every day for one week. On the first and seventh day of the study, participants complete surveys in order to assess their lifestyle and appetite. In addition, their heart rate and blood pressure are also recorded.

What are the possible benefits and risks of participating?
There are no direct benefits or risked involved with participating.

Where is the study run from?
OmniActive Health Technologies Ltd. (India)

When is the study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
The University of Tampa (USA)

Who is the main contact?
1. Dr Vijaya Juturu (scientific)
2. Dr Jacob Wilson (scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Vijaya Juturu

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07960

Type(s)
Scientific

Contact name
Dr Jacob Wilson

Contact details
The University of Tampa’s exercise physiology laboratories
Human Performance Laboratories
Tampa
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FL 33606

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAPOL001_2015

Study information

Scientific Title
Capsaicinoids reduces appetite response: an open label study in free living population

Study objectives

The aim of this study is to examine the effects of capsaicinoids (CAPs) supplementation for a week on resting heart rate, diastolic and systolic blood pressure, willingness to exercise, duration and intensity of exercise, and appetite.

Ethics approval required
Old ethics approval format

Ethics approval(s)
VJ University of Tampa, 10/06/2015, ref: 13-07

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

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
Capsaicinoids supplementation

Interventions
Following provision of informed consent, all participants are given 100 mg Capsimax (which contains 2 mg capsaicinoids) to take with their breakfast meal for 7 days.

On the first day of the study period, participants complete pre and general surveys on their life style, appetite measures as well as having their resting heart rate and blood pressure measurements recorded. On the final day (day 7), participants complete post survey questionnaires and have their resting heart rate and blood pressure recorded.

Intervention Type
Supplement

Primary outcome measure
1. Appetite is measured using VAS questionnaires and subjective questionnaires at baseline and 7 days
2. Exercise habits are measured using surveys designed for the purpose of this study at baseline and 7 days

Secondary outcome measures
1. Resting heart rate is measured manually by researchers at baseline and 7 days
2. Diastolic and systolic blood pressure is measured using a sphygmomanometer at baseline and 7 days

Overall study start date
31/05/2015

Completion date
06/08/2015

Eligibility

Key inclusion criteria
1. Aged between 19-51 years
2. BMI of less than 40kg/m2
3. Provision of written informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Chronic disease/condition
2. Pregnancy or lactation
3. No dietary supplement consumption

Date of first enrolment
15/06/2015

Date of final enrolment
30/07/2015

Locations

Countries of recruitment
United States of America

Study participating centre

The University of Tampa
Department of Health Sciences and Human Performance
401 W. Kennedy Blvd.
Tampa
United States of America
33606-1490

Sponsor information

Organisation
OmniActive Health Technologies Ltd.

Sponsor details
Cybertech House, First Floor
J.B. Sawant Road
Wagle Industrial Estate
Thane (West)
India
400 604

Sponsor type
Industry

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 peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/02/2017		Yes	No