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Tolerability and safety of capsaicinoids from capsicum extract (Capsimax®)

Submission date
02/06/2015

Recruitment status
No longer recruiting

Registration date
08/06/2015

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
Capsaicinoids are an active component of chilli peppers. They have been well researched and a number of clinical studies have suggested that they have health benefits. However, a person would have to consume 10g red hot peppers every day to gain any of these benefits. Capsimax™ is a supplement that contains capsaicinoids in beadlet form. This study will test how safe and tolerable Capsimax™ is when taken by healthy women compared with a placebo.

Who can participate?
Healthy women aged between 25 and 55.

What does the study involve?
The participants are randomly allocated to one of two groups. Those in group 1 (intervention) are given Capsimax™ supplemented with increasing levels of capsaicinoids every week for 5 weeks. For week 1, the capsaicinoids dose is 2mg, week 2, 4mg, week 3, 6mg, week 4, 8mg and, finally, week 5, 10mg. Participants in group 2 (control) are given a placebo for 5 weeks.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Medicus Research CRO, Staywell Research Clinical Research Site, California (USA)

When is the study starting and how long is it expected to run for?
July 2011 to October 2011

Who is funding the study?
OmniActive Health Technologies Inc (USA)

Who is the main contact?
Dr Vijaya Juturu

Contact information

Type(s)
Scientific

Contact name
Dr Vijaya Juturu

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OMNI1000 (Tolerability Phase)

Study information

Scientific Title
Tolerability and safety of capsaicinoids from capsicum extract (Capsimax®): a randomized, double-blind, placebo-controlled, dose-finding, adaptive-design study

Study objectives
The purpose of this study was to evaluate the tolerability and impact on metabolic measures of escalating doses of the Capsimax™ product for over 5-week period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Copernicus Group Independent Review Board (Cary, NC), 13/01/2011

Study design
Randomized double-blind placebo-controlled dose-finding adaptive design study

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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
Tolerability and dose testing

Interventions
Two randomly allocated groups:
1. Group 1 (intervention) given Capsimax™ supplemented with increasing levels of capsaicinoids every week for 5 weeks.
Week 1 – initiation of dose level 2 (2mg)
Week 2 – initiation of dose level 3 (4mg)
Week 3 – initiation of dose level 4 (6mg)
Week 4 – initiation of dose level 5 (8mg)
Week 5 – initiation of dose level 6 (10mg)
Week 6 – end of study
2. Group 2 (control) given a placebo for 5 weeks.

Intervention Type
Supplement

Primary outcome measure
Tolerability assessments and adverse event reporting
1. Weight
2. BMI
3. Blood Pressure

Secondary outcome measures
1. CBC
2. CMP
3. Fasting insulin
4. Cholesterol Panel (Total Cholesterol, LDL, HDL, TG)
5. C-Peptide
6. HS-CRP
7. Glycerol
8. Free Fatty Acids
9. HbA1c

Overall study start date
22/07/2011

Completion date

12/10/2011

Eligibility

Key inclusion criteria
1. Healthy female subjects between 25 and 55 years of age
2. Body mass index (BMI) between 25 and 34.9 kg/m2 (inclusive)
3. Judged by the Investigator to be in general good health on the basis of medical history
4. Subject understands the study procedures and signs forms providing informed consent to participate in the study and authorization for release of relevant protected health information to the study investigator
5. Subject agrees to all study visits and procedures
6. Subject agrees to travel to DEXA facility location
7. Sedentary lifestyle: not being physically active greater than 3 days/week for 20 minutes each time for the previous 6 months, and not participating in regular resistance exercise

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
Tolerability Sub-Study 12 Subjects were enrolled in the tolerability phase of the study

Key exclusion criteria
1. Regular ingestion of chili peppers (raw or powdered form), black pepper, or ginger, or foods known to contain chili peppers, black pepper or ginger more than 3 times per week on average
2. Known allergy to chili pepper
3. Known allergy to any foods
4. Consumption of >3 servings per day of caffeine containing beverages
5. Any significant GI condition that would potentially interfere with the evaluation of the study product including but not limited to inflammatory bowel disease (Ulcerative Colitis or Crohn's), history of frequent diarrhea, history of surgery for weight loss (including gastric bypass or lapband), history of perforation of the stomach or intestines, gastroparesis, clinically important lactose intolerance.
6. Clinically significant renal, hepatic, endocrine (including diabetes mellitus), cardiac, pulmonary, pancreatic, neurologic, hematologic, or biliary disorder
7. History or presence of cancer in the prior two years, except for non-melanoma skin cancer
8. Recent history of (within 12 months) or strong potential for alcohol or substance abuse
9. Participation in a clinical study with exposure to any non-registered drug product within 30 days prior
10. Individual has a condition the Investigator believes would interfere with her ability to provide informed consent, comply with the study protocol, which might confound the interpretation of the study results or put the person at undue risk
11. Diabetes requiring medication
12. Untreated or unstable Hypothyroidism
13. Weight loss or gain of at least 10 pounds in the last 3 months

14. Participation in a formal weight loss program or diet plan in the last 3 months
15. Clinically significant abnormal Physical Examination
16. Subjects with active eating disorder including anorexia nervosa, bulimia, and/or obsessive compulsive eating disorders
17. Central Neurological disorders including but not limited to Spinal cord injuries, multiple sclerosis, Parkinson disease
18. Pregnant, lactating, or unwilling to use adequate contraception during the duration of the study
19. Currently taking antacids or acid-blocking medications
20. Currently taking anti-coagulant medications (including but not limited to aspirin, ticlid, heparin, and Coumadin)
21. Currently taking MAO-Inhibitors
22. Currently taking herbal products or dietary supplements – subjects who are willing to wash out of these products may be included after a 2 week washout period

Date of first enrolment
22/07/2011

Date of final enrolment
12/10/2011

Locations

Countries of recruitment
United States of America

Study participating centre
Medicus Research CRO
Staywell Research Clinical Research Site
Northridge
California
United States of America
91325

Sponsor information

Organisation
OmniActive Health Technologies Inc. (USA)

Sponsor details
67 East Park Place
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Morristown
United States of America
07960

Sponsor type
Industry

Website
http://www.omniactives.com/

ROR
https://ror.org/024e1pj18

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
30/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No