

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

Submission date 02/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 31/07/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

ORCID ID

<https://orcid.org/0000-0002-7397-715X>

Contact details

67 East Park Place
Morristown
United States of America
07960

Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

Tolerability assessments and adverse event reporting

1. Weight

2. BMI

3. Blood Pressure

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

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