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The effect of curcumin on blood circulation for healthy vasodilation

Submission date	Recruitment status	[_] Prospectively registered
14/12/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/12/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2023	Circulatory System	

Plain English summary of protocol

Background and study aims

Cardiovascular disease (CVD) is a general term used to describe disease of the heart or blood vessels. One of the best ways to predict whether someone is likely to develop CVD is by looking at the state of the endothelium (inner lining of blood vessels). In people who are at risk of developing CVD, the endothelium of their blood vessels is not able to expand (vasodilation) and contract (vasoconstriction) as well as it should do. For thousands of years, curcuminoids have been used in Eastern medicine to treat a range of health problems. Curcuminoids are natural chemicals found in the spice turmeric, which have been shown to have many properties which benefit health. The aim of this study is to find out whether curcuminoid supplements has an effect on endothelial function in mediated vasodilation (a technique to test how well arteries are able to expand after compression).

Who can participate?

Healthy adults between the ages of 19 and 29.

What does the study involve?

Participants are randomly allocated to one of three groups. Participants in the first group take capsules containing 50mg of curcuminoids every day for 8 weeks. Participants in the second group take capsules containing 200mg of curcuminoids every day for 8 weeks. Participants in the third group take capsules containing a placebo (dummy) every day for 8 weeks. At the start of the study and after 8 weeks, all participants undergo a flow-mediated dilation (FMD) test. This is done by inflating a blood pressure cuff around their arm to stop blood flow in the arm for 5 minutes. When the cuff is released, the diameter (width) of the artery is monitored for 3 minutes in order to see how long it takes to dilate back to its normal diameter.

What are the possible benefits and risks of participating?

Participants are given access to the results of their ultrasound scans and so can seek treatment if a problem with their circulation is discovered. There are no notable risks of taking part in the study, although participants may experience some discomfort when the blood pressure cuff is inflated around their arm.

Where is the study run from?
Texas Christian University (USA)

When is the study starting and how long is it expected to run for?
November 2014 to May 2015

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

Who is the main contact?
Dr Vajaya Juturu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
OAHTCUR002-2014

Study information

Scientific Title
Effects of curcuminoids on endothelial function in young, healthy individuals

Study objectives
The aim of this study is to investigate the effect of 50 mg curcuminoids and 200 mg curcuminoids on flow mediated vasodilation a predictive marker for endothelial function and important assessment for cardiovascular risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Texas Christian University Institutional Review Board, 30/08/2014, ref: 1410-105-1410

Study design
Double-blind randomized placebo-controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Assessment of cardiovascular risk

Interventions
Participants are randomly allocated to one of three groups:
Group 1: Participants ingest 50 mg of curcuminoids every day for 8 weeks
Group 2: Participants ingest 200 mg of curcuminoids every day for 8 weeks
Group 3: Participants ingest a placebo every day for 8 weeks

At baseline and 8 weeks, participants in all groups undergo a flow-mediated dilation (FMD) test. The FMD procedure will be performed using an Acuson Aspen Ultrasound System in order to determine the diameter of the brachial artery. All FMD measures will be taken in a quiet, temperature controlled room after a period of rest (20 minutes). An initial ultrasound image of the brachial artery diameter will be obtained and used as a baseline measurement. A blood pressure cuff will then be placed on the participant's forearm and inflated to 50 mmHg above their resting systolic blood pressure, as determined during measurement of vital signs, to occlude blood flow to the hand and forearm for a 5-minute period. After the cuff is released, the artery diameter will be monitored for 3 minutes using the ultrasound unit. The video clips will be analyzed using Medical Imaging Software which provides an average diameter for each clip. The final data will be expressed as the peak diameter compared to the pre-occlusion baseline diameter, reported in both absolute units (mm) and as a percent change.

Baseline artery diameter and maximal brachial artery diameter post-occlusion will be used to calculate FMD pre- and post-supplementation. In addition, a subset of analysis will be performed on subjects with ≤7% FMD to see the effect of two treatments compared to placebo.

Intervention Type
Supplement

Primary outcome(s)
1. Flow mediated dilation is measured using ultrasound scanning at baseline and 8 weeks in all participants
2. Flow mediated dilation is measured using ultrasound scanning at baseline and 8 weeks in a subset of participants who had an FMD of 7% or lower

Key secondary outcome(s))
None

Completion date

30/05/2015

Eligibility

Key inclusion criteria
1. Aged between 19 and 29 years inclusive
2. Meet the minimum recommendations for health and fitness by the American College of Sports Medicine
3. Non-smoking
4. Free from any musculoskeletal, medical or metabolic contraindications to exercise
5. Have not consumed any nutritional supplements and/or ergogenic aids for the preceding 9-week period and/or not have taken any anti-inflammatory medications for the previous month
6. Good general health as determined by a health history questionnaire
7. Female participamt must be currently taking oral contraceptive or post-menopausal (i.e. not pregnant)
8. Able to provide written and dated informed consent
9. Willing and able to comply with the protocol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Oarticipation in another clinical trial or consumption of investigational product within the previous thirty days
2. History of alcohol and/or drug abuse in the past 6 months or intends to consume either over the course of the study
3. Reported history of chronic or presence of treated or untreated bleeding disorder, diabetes mellitus, high blood pressure (systolic BP> 140 and/or diastolic BP> 90), thyroid disease, tachyarrhythmia, heart disease, kidney disease, or liver disease
4. Currently suffers from sleep disorder and/or has a known history of (or is currently being treated for) clinical depression, eating disorder(s) or any other psychiatric condition(s), which in the opinion of the investigator, might put the subject at risk and/or confound the results of the study
5. Subject has a known allergy or sensitivity to any ingredient in the test product
6. Any medical condition or uses any medication, nutritional product, dietary supplement or program, which in the opinion of the investigator, might interfere with the conduct of the study or place the subject at risk
7. History of difficulty swallowing large pills or tablets
8. Creatine use within 9 weeks prior to screening
9. History of orthopedic injury or surgery within the last 6 months
10. Has a contraindication to exercise utilized in research design
11. Subject has self-reported an abnormal resting ECG

12. Investigator is uncertain about subject’s capability or willingness to comply with the protocol requirements

Date of first enrolment
10/11/2014

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
United States of America

Study participating centre
Texas Christian University
2800 South University Drive
Fort Worth
United States of America
76129

Sponsor information

Organisation
OmniActive Health Technologies Inc.

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
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Blood flow results	01/07/2016		Yes	No
Results article	Effects on performance decrements following muscle-damaging exercise	23/07/2019	10/01/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes