

# The effect of curcumin on blood circulation for healthy vasodilation

<b>Submission date</b> 14/12/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/01/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English Summary

### 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**  
Dr Vijaya Juturu

**ORCID ID**  
<http://orcid.org/0000-0002-7397-715X>

**Contact details**  
OmniActive Health Technologies Inc.  
67 East Park Place  
Suite 500  
Morristown  
Morristown  
United States of America  
07960

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
OAHTCUR002-2014

## Study information

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

**Study hypothesis**

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

### **Secondary study design**

Randomised controlled trial

### **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.

### **Condition**

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  $\leq 7\%$  FMD to see the effect of two treatments compared to placebo.

### **Intervention Type**

Supplement

### **Primary outcome measure**

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

### **Secondary outcome measures**

None

### **Overall study start date**

02/11/2014

### **Overall study end date**

30/05/2015

## **Eligibility**

### **Participant 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 participant 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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

N=60 (20 per treatment arm)

## **Participant exclusion criteria**

1. Participation 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

## **Recruitment start date**

10/11/2014

## **Recruitment end date**

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.

**Sponsor details**

67 East Park Place  
Suite 500  
Morristown  
United States of America  
07960

**Sponsor type**

Industry

**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 presentation of results data at relevant conferences and publication of results in a peer reviewed journal.

**Intention to publish date**

31/12/2017

**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?
<a href="#">Results article</a>	Blood flow results	01/07/2016		Yes	No
<a href="#">Results article</a>	Effects on performance decrements following muscle-damaging exercise	23/07/2019	10/01/2023	Yes	No