

# Bioavailability of oral curcumin ingestion

<b>Submission date</b> 16/03/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/07/2018	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Curcumin, a bright yellow spice, is widely grown in South-East Asian countries. It has a long history of use in food as a spice, mainly as an ingredient in many varieties of curry powders and sauces. Curcumin is widely used to colour many foods. Several forms of curcumin are available on the market but their absorption by the body has not been studied for all of the forms. The aim of this study is to measure the absorption of two different curcumin supplements in healthy volunteers.

### Who can participate?

Healthy volunteers aged between 18 and 55

### What does the study involve?

Participants are randomly allocated to take either a standard curcumin supplement or a new supplement with a glass of water. On the morning of the study, participants arrive having fasted for at least 10 hours. Blood samples are taken before they take the supplement and after 15 minutes, 30 minutes, 1, 2, 3, 4, 5, 6, 8, 12, and 24 hours. Participants record their diet for 3 days before and on the day of the study. A meal not containing curcumin is provided for lunch and dinner on the day of the study. Participants return 7 days later and the process is repeated with the other supplement. Blood samples are tested for levels of curcumin substances and are also stored for potential future testing.

### What are the possible benefits and risks of participating?

The results of this study will help people to choose the right supplement for better absorption. A possible risk is pain during the collection of the blood sample.

### Where is the study run from?

1. Texas Christian University (USA)
2. University of North Texas Health Science Center at Fort Worth (USA)

### When is the study starting and how long is it expected to run for?

June 2016 to August 2017

### Who is funding the study?

OmniActive Health Technologies Ltd (India)

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  
Suite 500  
Morristown  
United States of America  
07960

## Additional identifiers

**Protocol serial number**  
CUR004-16

## Study information

**Scientific Title**  
A randomized, double-blind, parallel study to compare the relative absorption of UltraSOL Curcumin and Curcumin reference product

**Study objectives**  
Despite its demonstrated effects, the benefit of curcumin is limited by its poor solubility, low absorption from the gut, rapid metabolism and rapid systemic elimination. While the major portion of ingested curcumin is excreted through the feces unmetabolized, the small portion that is absorbed is extensively converted to its water-soluble metabolites, glucuronides and sulfate, and excreted. The purpose of this study was to assess the bioavailability of two different oral curcumin formulations: a curcumin reference (standard) and a new, natural curcumin formulation (UltraSOL Curcumin (OmniActive) over the course of 24 hours (0, 1, 2, 3, 4, 5, 6, 8, 12, 24 hours).

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Texas Christian University institutional review board, 07/08/2016, ref: 1605-071-1607

**Primary study design**

Interventional

### **Study design**

Single-dose randomized double-blind crossover design

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Bioavailability of two different oral curcumin formulations

### **Interventions**

Subjects will be randomised to receive one of two curcumin supplements: Curcumin standard formulation (1800 mg) or UltraSOL Curcumin (376 mg), administered with a glass of water. After a 7-day washout period, this process will be repeated with the other supplement for the two remaining study visits.

On the morning of supplementation, subjects will arrive having fasted for at least 10 hours. A baseline blood sample will be drawn prior to ingestion of supplement (0 hours). Thereafter, blood will be sampled at 15 minutes, 30 minutes, 1, 2, 3, 4, 5, 6, 8, 12, and 24 hours post-ingestion. Subjects will record dietary intake for 3 days prior to and on the day of experimental protocol. A non-turmeric containing meal will be provided for lunch and dinner on the day of experimentation. Subjects will return 7 days after first experimental protocol to participate under alternative treatment. Blood from timepoints (0, 1, 2, 3, 4, 5, 6, 8, 12, 24 hours) will subsequently be measured for curcuminoids (curcumin, demethoxycurcumin, bisdemethoxycurcumin, tetrahydrocurcumin) by HPLC. Blood from timepoints 15 minutes and 30 minutes, as well as additional samples from all other time points will be stored for potential future analysis of free curcuminoids (without the addition of glucuronidase). Descriptive statistics (mean, standard deviation) will be calculated. Area under the curve will be calculated in accordance with the trapezoidal method from 0 to 12 h and 0 to 24 h. Concentration max (C<sub>max</sub>) will be identified as the maximum concentration achieved over the 24 h period with corresponding time (t<sub>max</sub>).

### **Intervention Type**

Supplement

### **Primary outcome(s)**

Plasma levels of major curcuminoids (curcumin, demethoxycurcumin, bisdemethoxycurcumin and tetrahydrocurcumin) will be evaluated at 0, 1, 2, 3, 4, 5, 6, 8 and 12 hours and 24 h. Peak plasma concentrations (T<sub>Max</sub>), areas under the plasma concentration-time curves (AUC<sub>0-6h</sub>, AUC<sub>0-12h</sub> and AUC<sub>0-24h</sub>), C<sub>Max</sub> and t<sub>max</sub> will be calculated. Relative absorption at 24h time point is helpful to observe normalization and safety of the product

### **Key secondary outcome(s)**

None

### **Completion date**

30/08/2017

## **Eligibility**

**Key inclusion criteria**

1. Normal healthy individuals
2. Age 18-55
3. Males and females
4. Must be able to perform required testing
5. Participants agreed to sign an informed consent form

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

55 Years

**Sex**

All

**Key exclusion criteria**

1. Pregnancy
2. Use of prescription medications
3. Gastrointestinal conditions
4. Diabetics
5. Alcohol and/or substance abuse history, and/or allergies to turmeric or curcumin
6. Subjects consuming any foods or supplements containing curcumin

**Date of first enrolment**

25/08/2016

**Date of final enrolment**

30/10/2016

**Locations****Countries of recruitment**

United States of America

**Study participating centre**

**Texas Christian University**

Harris College of Nursing & Health Sciences

Department of Kinesiology

TCU Box 297730

Fort Worth  
United States of America  
76129

**Study participating centre**  
**University of North Texas Health Science Center at Fort Worth**  
Fort Worth  
United States of America  
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## Sponsor information

**Organisation**  
OmniActive Health Technologies Ltd

**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

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jonathan Oliver or Dr Vijaya Juturu

**IPD sharing plan summary**

Available on request