

# Absorption of different curcumin formulations

<b>Submission date</b> 30/08/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/09/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/07/2018	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Curcuma longa L is widely cultivated 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, where curcumin from turmeric is a main colouring substance. Curcumin is widely used to color 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. Hence, we plan to study different curcumin supplements and their absorption in humans.

### Who can participate?

Healthy people aged between the 18 and 55 can participate in the study.

### What does the study involve?

Participants will be randomly assigned to have four types of curcumin supplements with a glass of water. Following consent, each participant will complete four visits. Participants will be given a different supplement at each visit. Each visit will be separated by at least 7 days and will follow identical study procedures, except for the consumption of a different curcumin supplement. Blood samples will be drawn at various intervals after taking in the supplements and will be tested for curcumin components. After the 4-hour and 8-hour blood samples have been drawn, a turmeric-free meal will be provided. Both the investigators and the participants will not know which supplement is consumed during each visit.

### 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?

Increnovo LLC, USA.

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

The study ran from May to July 2013.

### Who is funding the study?

OmniActives Health Technologies Ltd, India.

Who is the main contact?  
Dr Vijaya Juturu  
v.juturu@omniactives.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Ralf Jaeger

**Contact details**  
Increnovo LLC  
2138 E Lafayette Place  
Milwaukee  
United States of America  
53202

## Additional identifiers

**Protocol serial number**  
Increnovo 13-07 [OAHTCUR2013]

## Study information

**Scientific Title**  
Comparative absorption of different curcumin formulations

**Study objectives**  
More and more preclinical studies support the idea that curcumin, a plant-derived natural polyphenol, could be a promising treatment for various chronic diseases. However, poor bio-availability has limited its efficacy in clinical trials. Very limited data is available on different curcumin formulations. The techniques and methods employed to produce these formulations may affect the bio-availability of the curcumin. We hypothesized that relative absorption of curcumin is very important to influence efficacy.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Spartans, The University of Florida Tampa approved protocol on Feb7, 2013 [Ref: 13-07].

**Study design**  
Randomized single-center single dose cross-over study

**Primary study design**  
Interventional

**Study type(s)**

Diagnostic

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

N/A

**Interventions**

Frequency: Single dose, randomized, double blinded, cross-over study design; Dose: 376 mg for (BCM-95® [Dolcas], Meriva® [Indena], and Curcumax UltraSol Dry Nutrient System™ [DNS] [OmniActive]), and 1800 mg for C3 Complextrade mark, (Sabinsa Corporation).

Intervention: Subjects will be administered with curcumin supplements.

Four treatments [C3 Complextrade mark, (Sabinsa Corporation), BCM-95® (Dolcas), Meriva® (Indena), and Curcumax UltraSol Dry Nutrient System™ (DNS) (OmniActive)] will be administered with a glass of water. After a 7-day washout period, this process will be repeated for the two remaining study visits. Subjects will be administered a different treatment than the previous visit, until all four treatments will be administered. The blood plasma samples will be evaluated for curcuminoids [curcumin, demethoxycurcumin, and bisdemethoxycurcumin] and tetrahydrocurcumin. Prior to testing, each volunteer underwent screening and the consent visit to ensure eligibility and voluntary willingness to participate. Following consent, each volunteer completed 4 treatments each in a randomized, double-blinded order separated by at least 7 days. A baseline blood sample was collected and one of four treatment dosages of curcumin was consumed with water. Blood samples will be drawn at 1, 2, 3, 4, 5, 6, 8 and 12 hours intervals following product consumption. After the 4-hour and 8-hour blood samples have been drawn, a turmeric-free meal will be provided. Each subsequent trial will be separated by at least 7 days as a washout period and followed identical study procedures, except for the consumption of a different curcumin formulation. Product formulations will be blinded to both the investigators and the volunteers will be coded so that neither knew which formulation is consumed during each trial.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Curcumin

**Primary outcome(s)**

1. Peak plasma concentrations (TMax),
2. Areas under the plasma concentration-time curves (AUC0-6h, AUC0-12h and AUC0- $\alpha$ ), CMax and t1/2

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. Peak plasma concentrations (TMax), areas under the plasma concentration-time curves (AUC0-6h, AUC0-12h and AUC0- $\alpha$ ), CMax and t1/2 will be calculated.

**Key secondary outcome(s)**

None

**Completion date**

06/07/2013

## Eligibility

**Key inclusion criteria**

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

**Participant type(s)**

Patient

**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**

02/05/2013

**Date of final enrolment**

06/07/2013

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**  
**Increnovo LLC**  
Milwaukee  
United States of America  
53202

## **Sponsor information**

**Organisation**  
OmniActive Health Technologies (India and 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**  
Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	24/01/2014		Yes	No