

# Analysis of different innovative formulations of curcumin for improved relative oral bioavailability

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 29/12/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The spice turmeric has been used for centuries throughout Asia for medicinal purposes, especially in the traditional Ayurvedic approach to nutrition. Curcumin is a substance found in turmeric. However, curcumin is not absorbed by the body very effectively. Different formulations of curcumin are already on the market, but haven't been examined under the same study conditions. The aim of this study is to analyze four different formulations of curcumin in one clinical setting.

### Who can participate?

Healthy people aged between 18 and 35.

### What does the study involve?

Participants are supplemented with visually identical gel capsules of each of the four supplements. Blood samples are taken before taking the supplements and hourly for 12 hours afterwards and analyzed to determine the levels of curcumin in the blood.

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

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

### Where is the study run from?

Increnovo LLC (USA).

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

May to July 2013.

### Who is funding the study?

Wacker Chemie AG (Germany).



Who is the main contact?  
Dr Helmut Reuscher  
helmut.reuscher@wacker.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Martin Purpura

**Contact details**  
Increnovo LLC  
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53202

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
WAC\_CUR01\_2013

## Study information

**Scientific Title**  
Analysis of different formulations of curcumin for improved relative oral bioavailability

**Study objectives**  
Turmeric has been widely used for centuries and is a well-known substance used in the traditional Ayurvedic approach to nutrition. Modern science has provided a solid basis for such uses and current clinical trials make curcumin, the main polyphenol derived from turmeric, one of the best investigated natural compounds to date. Strong molecular evidence has been published for its potency to target e.g. multiple inflammatory diseases. However, curcumin cannot achieve its optimum therapeutic outcomes due to its low solubility and poor bioavailability. Curcumin has shown significant efficacy in cell culture studies but has shown limited efficacy in clinical studies when administered in conventional oral formulations. We hypothesized that relative absorption of oral curcumin formulations is very important to influence efficacy. There is little and very diverse data available on bioavailable curcumin formulations.

**Ethics approval required**



Old ethics approval format

**Ethics approval(s)**

The University of Florida Tampa IRB, 07/02/2013, Ref: 13-07

**Study design**

Randomized single-center single-dose cross-over study

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

Other

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Nutritional supplement

**Interventions**

Four curcumin supplement formulations were used (BCM-95® [Dolcas], Meriva® [Indena], C3 Complex™ [Sabinsa Corporation] and CAVAMAX® W8 Curcumin/CAVACURMIN® [Wacker Chemie AG].

All volunteers were supplemented with visually identical 6 hard gel capsules of each of the four study materials per setting, resulting in 376 mg of total curcuminoids for CAVAMAX® W8 Curcumin/CAVACURMIN®, BCM-95® and Meriva® and 1,800 mg of total curcuminoids for StdC (C3 Complex™) in accordance with the study dosage established by Cuomo et al.

Each dose was separated by a washout period of at least 7 days and blood plasma curcumin levels were assessed continuously for 12 hours following each treatment.

First the baseline blood sample was obtained, followed by one of four treatment dosages of curcumin which were consumed with water. Further blood samples were then drawn at the time points of 1, 2, 3, 4, 5, 6, 8 and 12 hours following product supplementation. Each time after the 4-hour and 8-hour blood sample draw, a low-fat and turmeric-free standardized meal was delivered. All subjects completed 4 trials with 9 blood draws each in a randomized, double-blinded order. Blood plasma samples were analyzed by tandem mass spectrometry detection to determine curcumin, demethoxycurcumin, and bisdemethoxycurcumin and tetrahydrocurcumin levels.

**Intervention Type**

Supplement

**Primary outcome measure**



1. Peak plasma concentrations Tmax (h)
2. Area under the plasma concentration time-curve (AUC 0-12), Cmax (ng/mL) and T1/2 (h)

Plasma levels of 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 (AUC0-12h), Cmax, t1/2 and relative absorption will be calculated.

**Secondary outcome measures**

None

**Overall study start date**

02/05/2013

**Completion date**

06/07/2013

## Eligibility

**Key inclusion criteria**

1. Healthy individuals
2. Age: 20-35 years
3. Males and females
4. Participants agreed to sign an informed consent form
5. Participants must be able to perform required testing

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

12

**Key exclusion criteria**

1. Consuming any curcumin-containing supplements or foods for two weeks prior to testing
2. History of any of the following: hyperacidity, gastric/duodenal ulcers, gastrointestinal problems, gallbladder issues
3. Use of any blood thinners/anti-thrombotic agents or NSAIDS
4. Prior use of blood sugar-lowering agents, H2 blockers, or proton pump inhibitors
5. Known allergies to soy
6. Diabetics
7. Pregnancy

**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

United States of America

53202

## Sponsor information

**Organisation**

Wacker Chemie AG (Germany)

**Sponsor details**

Hanns-Seidel-Platz 4

Muenchen

Germany

81737

**Sponsor type**

Industry

**Website**

[www.wacker.com](http://www.wacker.com)

**ROR**

<https://ror.org/01h21cs69>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Wacker Chemie AG (Germany)



# Results and Publications

## Publication and dissemination plan

To be confirmed at a later date

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not expected to be made available