

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

Submission date 19/11/2015	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 29/12/2015	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 29/12/2015	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ 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
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Contact information

Type(s)
Scientific

Contact name
Dr Martin Purpura

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Increnovo LLC
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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomized single-center single-dose cross-over study

Study type(s)

Diagnostic

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(s)

1. Peak plasma concentrations T_{max} (h)
2. Area under the plasma concentration time-curve (AUC 0-12), C_{max} (ng/mL) and T_{1/2} (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 (T_{Max}), areas under the plasma concentration-time curves (AUC_{0-12h}), C_{max}, t_{1/2} and relative absorption will be calculated.

Key secondary outcome(s)

None

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

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

Funder(s)**Funder type**

Industry

Funder Name

Wacker Chemie AG (Germany)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available