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

Submission date
19/11/2015

Recruitment status
No longer recruiting

Registration date
29/12/2015

Overall study status
Completed

Last Edited
29/12/2015

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Contact details
Increnovo LLC
2138 E Lafayette Place
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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 ComplexTM [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 ComplexTM) 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

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