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# Absorption of different curcumin formulations

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 30/08/2013 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 13/09/2013 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 31/07/2018 | Other | |

## 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

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled 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
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 measure
1. Peak plasma concentrations (TMax),
2. Areas under the plasma concentration-time curves (AUC0-6h, AUC0-12h and AUC0-α), 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-α), CMax and t1/2 will be calculated.

### Secondary outcome measures
None

### Overall study start date
02/05/2013

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
55 Years

### Sex
Both

### Target number of participants
12

### 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)

### Sponsor details
c/o Vijaya Juturu
67 East Park Place, Suite 500
Morristown
United States of America
07960

### Sponsor type
Industry

### Website
http://www.omniactives.com

### 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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**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? |
|---|---|---|---|---|---|
| Results article | results | 24/01/2014 | | Yes | No |