

Absorption of different curcumin formulations

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

Type(s)
Scientific

Contact name
Dr Ralf Jaeger

Contact details
Increnovo LLC
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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].

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

N/A

Interventions

Frequency: Single dose, randomized, double blinded, cross-over study design; Dose: 376 mg for (BCM-95® [Dolcas], Meriva® [Indena], and Curcuma 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 Curcuma 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 (T_{Max}),
2. Areas under the plasma concentration-time curves (AUC_{0-6h}, AUC_{0-12h} and AUC_{0-∞}), C_{Max} and t_{1/2}

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 (T_{Max}), areas under the plasma concentration-time curves (AUC_{0-6h}, AUC_{0-12h} and AUC_{0-∞}), C_{Max} and t_{1/2} 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?
Results article	results	24/01/2014		Yes	No